IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC., Defendants.	)	C. A. No.: 21-1317-GBW-SRF **JURY TRIAL DEMANDED** [redacted] [redacted] **Redacted - Public Version Filed on: July 19, 2023**

LETTER TO THE HONORABLE SHERRY R. FALLON
FROM MELANIE K. SHARP REGARDING DEFENDANTS' LETTER (D.I. 236)

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Attorneys for Sight Sciences, Inc.

Dated: July 11, 2023

Dear Judge Fallon:

The Court should deny Defendants' motion to compel Sight to produce attachments referenced in lesser-included content of produced emails[1] for numerous reasons: (1) Sight has complied with the carefully-negotiated terms of the ESI Order (D.I. 49), which requires production of full **families, not full email threads**; (2) Defendants' attempt to retroactively modify the ESI Order is unfairly burdensome to Sight and forfeited because it is raised too late; (3) Defendants have suffered no prejudice because Sight has agreed to produce a reasonable number of specifically-identified attachments requested by Defendants, and none of the attachments identified have been material to Defendants' defenses in this case; and (4) compelling Sight to undertake a comprehensive re-review of its productions for attachments referenced in lesser-included emails would be disproportionate to the needs of the case, particularly at this post-fact discovery stage. In short, the Court should reject Defendants' efforts to contrive a discovery violation where none exists.[2]

First, Sight's document productions fully comply with the stipulated ESI Order negotiated by the parties and entered by the Court. D.I. 49; 6/15/2022 Docket Entry. The ESI Order provides: "Where documents with attachments are produced, they will be attached in the same manner as included in the original file. Unless documents contain solely Privileged Information, parties will produce complete Document **Families** where any portion of the Family contains relevant information." D.I. 49 ¶4(e) (emphasis added). "Family" is defined as "a group of documents that are maintained as a single unit in the ordinary course of business (*e.g.*, an email and its attachments)." *Id.*, ¶3(b). This is precisely what Sight has done—produced groups of documents as they are maintained in the ordinary course of business. For email threads, an attachment is only part of a document "family" when its parent document is the "last-in-time" email in the thread. *See* Ex. 1 (6/23/23 L. Strosnick Email); *see also* D.I. 226 at 4. Conversely, attachments to "earlier-in-time" emails in a thread are not ordinarily maintained as attachments to the last-in-time email. Defendants seem to argue that Sight must produce an attachment merely **referenced** in an earlier-in-time email when that attachment is **not** part of the produced email's family because that attachment is not attached to the last-in-time email in the thread. But neither the ESI Order nor the Delaware Default Standard (*see* D.I. 49 ¶1) requires Defendants' approach. Sight satisfied its obligations regarding discovery of ESI by collecting documents from disclosed custodial and non-custodial sources, running search terms provided by each party, reviewing the results, and producing the full **family** of any responsive document (regardless of whether the document was "last-in-time" or "earlier-in-time" within an email thread). *See* Delaware Default Standard for Discovery ¶¶3(a)-(b), 5(b); D.I. 49 ¶4(e). Contrary to what Defendants suggest, Sight does **not** agree that the attachments at issue are "relevant, responsive, and should be produced." *See* D.I. 236 at 1-2. Sight has already produced all family "attachments to responsive email threads" (*see* D.I. 236 at 1), and is not withholding any non-privileged, relevant, and responsive attachments.

[1] Defendants' description of these attachments as "missing attachments" is misleading. Defendants have not identified any produced emails that are "missing attachments"—the attachments in question are simply referenced in lesser-included content of produced emails.

[2] As noted in Sight's June 28 letter, Defendants prematurely and improperly raised this issue in their June 27 letter, before the parties reached impasse. D.I. 223 at 4; D.I. 226 at 4. The parties only reached impasse on June 28. Ex. 1 (6/28/2023 N. Frank Email); *see also id.* (6/26/2023 L. Strosnick Email) ("Lastly, we do not agree to add this issue as an amendment to your 6/23 joint motion for teleconference, as the parties are still conferring about it.").

The attachments that Defendants are requesting were not identified as responsive during Sight's document review because they did not hit on either party's search terms (and therefore were not reviewed) or were reviewed and determined to be non-responsive.

Second, Defendants forfeited their ability to demand production of non-family attachments to lesser-included emails by failing to raise this issue during ESI Order negotiations over a year ago. The ESI Order is silent regarding email threads, strings, chains, or the like (*see generally* D.I. 49); if Defendants wished to receive attachments to lesser-included emails, they could have negotiated for a provision to that effect.[3] Indeed, several ESI stipulations in this Court include such provisions. Ex. 2, *Morphosys AG v. Janssen Biotech, Inc.*, C.A. No. 16-221-LPS-CJB, D.I. 37-1 at 10 (D. Del. Sept. 23, 2016) (stipulating that "[t]o the extent a lesser-included email contains a nontrivial attachment not otherwise produced with the most-inclusive email, the Parties will produce or list on any required privilege log the lesser-included email and any accompanying attachment to the extent it otherwise would have been subject to production"); Ex. 3, *FlatFrog Lab'ys AB v. Promethean Ltd.*, C.A. No. 19-2246-MN, D.I. 75 at 8 (D. Del. Jan. 19, 2021) (same). By failing to propose such a provision during ESI Order negotiations in May and June 2022, Defendants forfeited this argument. It is far too late to retroactively alter the ESI Order. *E.g.*, *Mirtech, Inc. v. Agrofresh, Inc.*, C.A. No. 20-1170-RGA, 2023 WL 3996618, at *4 (D. Del. June 14, 2023) (citing *United States v. Dowdell*, 70 F.4th 134, 140 (3d Cir. 2023)) (holding that an argument is forfeited when a party fails to timely raise it). Defendants offer no justification for waiting until the last day of fact discovery to bring this dispute to the Court's attention.

Third, there is no prejudice to Defendants under these circumstances because Sight has cooperated in good faith to produce a reasonable number of specifically-identified non-family attachments referenced in email threads that Defendants requested before the close of fact discovery. Ex. 1 (6/22/2023 L. Strosnick Email) (detailing the steps undertaken to identify and produce attachments referenced in SGHT0031048 and -0031051); *id.* (6/26/2023 L. Strosnick Email). On June 29, Sight produced the attachments referenced in six additional documents identified on June 20, to the extent they could be located following a reasonable search and were not already produced. *See* Ex. 4 (6/29/2023 J. Douglas Email and attachment). Notably, none of the referenced attachments requested by Defendants have been material to their defenses in this case. For example, one identified email thread included an earlier-in-time email attaching three publicly-available articles, which Sight subsequently produced. Ex. 1 (6/20/2023 N. Frank Email) (identifying SGHT0030936); Ex. 6 (SGHT0030936) (email thread); Ex. 7 (SGHT0168062) (publication); Ex. 8 (SGHT0168069) (publication); Ex. 9 (SGHT0168078) (publication).[4]

Fourth, it would be unduly burdensome and disproportionate to the needs of this case to compel Sight to comb through its productions to locate copies of attachments referenced in earlier-in-time emails in produced email threads. This is particularly inappropriate given the stage of the case—fact discovery is closed. Sight substantially completed its collection, review, and production of

[3] In June 2022, Ivantis accepted Sight's proposed definition for "Family" without any edits, and chose not to propose any provision regarding email threading or production of attachments to lesser-included emails. Ex. 5 (6/6/2022 K. Li Email and ESI Redline attachment).

[4] Sight never suggested that "it is Defendants' burden to scour Sight's production and identify all missing attachments." *See* D.I. 236 at 1. Sight simply agreed to produce specific attachments that Defendants believed may be responsive but not produced. Ex. 1 (6/26/2023 L. Strosnick Email).

documents over four months ago. Sight already complied with the ESI Order by employing contract attorney reviewers (who have long since been released) and by searching for responsive documents using search terms formulated by both parties. It would be extremely time-consuming, costly, and wasteful to require Sight to restart its search for and review of attachments that were previously not collected or reviewed because they did not hit on either party's search terms or were already reviewed in other document families and found to be non-responsive.

Lastly, Defendants' attempt to belatedly alter Sight's eDiscovery obligations is inconsistent with their own document productions, which include numerous documents with no attachment that nonetheless reference a non-family attachment earlier in the thread. Ex. 10 (IVANTIS_SS_00166001) ("Please see attached"); Ex. 11 (IVANTIS_SS_00166303) ("Attached is a brief consulting agreement…"); Ex. 12 (IVANTIS_SS_00166426) ("[A]attached are all my add'l notes…"); Ex. 13 (IVANTIS_SS_00224381) ("Attached details sent to LDS on slides"); Ex. 14 (IVANTIS_SS_00355834) ("I have attached an older SOP for the perfusion testing…"); *see also* Ex. 1 (6/26/2023 L. Strosnick Email). Sight opposes any modification of the ESI Order at this late stage of discovery as unduly burdensome and forfeited, but to the extent that the Court orders Sight to produce any attachments referenced in lesser-included emails (which is not appropriate for the reasons explained above), Defendants should be required to do the same.

The case law cited by Defendants is unavailing. First, none of the cases involved an ESI Order with provisions similar to the ESI Order here. In *FrenchPorte IP, LLC v. C.H.I Overhead Doors, Inc.*, the parties agreed to use an eDiscovery technique called email threading to produce "only the most evolved responsive email in a thread," and further agreed to produce attachments "[w]here an earlier-in-thread email has a responsive attachment not contained within the most evolved responsive email."[5] Ex. 15, C.A. No. 2:21-2014, D.I. 27-1, ¶12 (C.D. Ill. Mar. 19, 2021). Here, Sight did **not** employ email threading to systematically exclude earlier-in-time emails from production, nor did the parties agree to produce attachments to earlier-in-time emails. And in the other cases, there was no ESI Order. *See, e.g.*, *Abu Dhabi Com. Bank v. Morgan Stanley & Co. Inc.*, C.A. No. 08-7508, 2011 WL 3738979, at *5 (S.D.N.Y. Aug. 18, 2011) ("A review of the legal authorities suggests that the best practice is for parties to discuss the production and logging of e-mails and attachments…and to reach agreement…. Regrettably, it does not appear from the Parties' Submissions that this was done."), *Report and Recommendation adopted*, 2011 WL 3734236 (S.D.N.Y. Aug. 24, 2011). Sight satisfied its obligations under the ESI Order by producing the full family of any responsive document. Second, all of the cases involved attachments to emails that were highly relevant. *Ariza v. Loomis Armored US, L.L.C.*, C.A. No. 13-419, 2014 WL 12611311, at *2 (M.D. La. Nov. 12, 2014); *FrenchPorte*, 2022 WL 18832042, at *3 (C.D. Ill. Dec. 19, 2022); *Abu Dhabi*, 2011 WL 3738979, at *2. Sight is not withholding any non-privileged attachments to relevant and responsive emails that it produced. If Sight produced a relevant and responsive email, then it also produced that email's full family.

In sum, the Court should deny Defendants' motion to compel Sight to produce non-family attachments referenced in lesser-included content of produced emails, which is not required under the ESI Order and is a thinly-veiled attempt by Defendants to derail the case schedule.

[5] *In re Actos Antitrust Litig.*, 340 F.R.D. 549 (S.D.N.Y. 2022) (D.I. 223 at 4) is also distinguishable because the parties agreed to use email threading to produce only the "most-inclusive email in a thread[,]" thereby "exclu[ding] [] lesser included emails from production." *Id.* at 550-52.

Respectfully,

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)

cc: All Counsel of Record (by e-mail)

30531556.1

EXHIBIT 1

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Wednesday, June 28, 2023 9:54 PM
To: Strosnick, Lauren; Teng, Austin C.; Rhyu, Michelle; Merideth, Vicki; cvilloslada@ycst.com; Armon, Orion; Gibbs, Tracy; Wood, Alissa; z/Sight Sciences Ivantis; Murdter, David; Douglas, Jeannine; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com; *msharp@ycst.com; Vanderwall, Cameron C.
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences; Mecham, Ross D
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Counsel:

We write to respond to your email and further address additional issues raised during today's meet-and-confer. In regard to today's meet-and-confer:

- We note that during the meet-and-confer the parties agreed we are at an impasse regarding Defendants' request that Sight produce missing attachments.
- We are currently looking into whether the requested final 2021 ADC presentation has been produced and agree to produce the identified 2018 ADC presentation, provided it can be located after a reasonable search. We are also investigating the existence of any final QBR presentations from 2021 and 2022, and, to the extent they are located after a reasonable search, agree to produce them.
- We also agree to produce the videos attached to IVANTIS_SS_00008079. As to IVANTIS_SS_00206389, as stated during the meet-and-confer, there are no video attachments, but we have located videos with similar file names in Defendants' files, which we will produce. During the meet-and-confer I identified SGHT0161937 as a document which also appears to have an attached video, and you agreed to produce that video.
- You agreed to confirm your interpretation and treatment of the term "outside counsel of record" when logging privileged communications. Please provide your interpretation by 10pm PT today.
- Concerning the 30(b)(6) designation of Catherine Truitt, you agreed you will be taking her deposition and that you will get back to us about deposition dates.
- Regarding N. DeLucia's 6/27 letter, you agreed to look for the identified repositories, and to the extent they have not been searched, search for and produce any responsive documents therein. You also agreed to search for and produce the identified Bates-numbered documents and any referenced attachments, lab notebooks, and/or Dropbox or Basecamp documents, the listed Badawi deposition documents, and product-specific cost allocations for OMNI.

As to your request regarding Alcon Topic 62, we disagree that Mr. Van Meter was not adequately prepared to testify. Mr. Van Meter answered each question asked of him regarding potential license terms and hypothetical royalties. *See* Van Meter Rough Dep. Tr. at 206:15-209:1. As such, Defendants do not agree to stipulate regarding trial testimony on this topic. Furthermore, because Mr. Van Meter was prepared to testify and because Sight had the full opportunity to question him about Topic 62, Defendants do not agree to provide an additional witness on this topic.

With regard to your requests concerning the laptop discussed by Mr. Van Meter during his deposition, we note that you raised these issues only an hour before the meet-and-confer. We will write to you separately regarding that issue.

Regards,

Noah Frank

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From: Strosnick, Lauren <lStrosnick@cooley.com>
Sent: Wednesday, June 28, 2023 6:44 PM
To: Frank, Noah S. <noah.frank@kirkland.com>; Teng, Austin C. <austin.teng@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

We write to memorialize a few items discussed during today's meet-and-confer. As discussed, given the close of fact discovery tomorrow, please confirm the following **by 8pm PT today** so we can timely raise these issues with the Court as needed:

- Whether Defendants are currently in possession of Dave Van Meter's Ivantis-issued laptop (or a backup thereof) discussed during his deposition yesterday;
- Whether Defendants have or will run Defendants' previously disclosed search terms and Sight's additional search terms (as agreed upon during the parties' negotiations) (all copied below) against the documents in Mr. Van Meter's laptop;
- Whether Defendants are refusing to produce presentations from [redacted] meetings most close in time to entering the Option to Acquire Ivantis in November 2018, and most close in time to exercising Alcon's option to acquire Ivantis in November 2021;
- Whether Defendants are refusing to produce final Alcon quarterly business reviews (QBRs) from 2021 and 2022 (after Alcon exercised its option to acquire Ivantis); and
- Whether Defendants possess agree to produce the videos referenced in IVANTIS_SS_00206389 (email from [redacted]), and the video that would have played at IVANTIS_SS_00008107 of IVANTIS_SS_00008079 (Hydrus Clinical Discussion featuring [redacted]).

Additionally, we note that Mr. Van Meter was not prepared to testify regarding any of the 30(b)(6) topics for which he was designated, and specifically on Alcon Topic 62 regarding "The terms You would have sought from Sight for a license to Any of the Patents- in-Suit, Any information that would have affected the royalty that You would have negotiated for such a license, and the royalty You would pay for such a license if one were offered." Please confirm that Alcon will not offer any testimony on this topic via declaration or live witness testimony in any court filing or at any hearing or at trial. To the extent Alcon will not stipulate, please provide witness availability on this topic.

Regarding N. DeLucia's 6/27 letter, Sight responds as follows:

- We will investigate whether there are additional DropBox or Basecamp repositories that constitute custodial ESI of Paul and David Badawi or non-custodial ESI of Sight Sciences and that have *not* already been collected and

contain non-duplicative information. To the extent they exist and have non-duplicative information, we will apply the parties' keyword searches to that data and produce responsive documents. We will provide an update on our investigation over the next few days when we learn more.

- Sight will investigate the Bates-numbered documents listed on page 2 of your letter and will produce referenced attachments, lab notebooks, and/or Dropbox or Basecamp documents, to the extent such documents exist and can be located after a reasonable search.
- Sight will produce the Badawi deposition documents identified on page 2 of your letter, to the extent they have not already been produced.
- Sight will produce product-specific cost allocations for OMNI to the extent such records exist and can be generated from Sight's financial system.

Thanks,
Lauren

***

Search terms for Dave Van Meter's laptop

- "1:21-cv-01317" OR 01317 OR ((Sight Sciences OR Site Sciences OR Sight Science OR Site Science) W/5 (lawsuit OR litigation OR suit OR case OR sued))
- (10314742 OR (742 w/3 patent) OR 8287482 OR (482 w/3 patent) OR 9370443 OR (443 w/3 patent) OR 9486361 OR (361 w/3 patent) OR 11389328 OR (328 w/3 patent) OR 7909789 or (789 w/3 patent))
- (10314742 OR (742 w/3 patent) OR 8287482 OR (482 w/3 patent) OR 9370443 OR (443 w/3 patent) OR 9486361 OR (361 w/3 patent) OR 11389328 OR (328 w/3 patent) OR 7909789 or (789 w/3 patent)) W/10 (purchase OR buy OR sell OR sale OR acquire OR license)
- (10314742 OR (742 w/3 patent) OR 8287482 OR (482 w/3 patent) OR 9370443 OR (443 w/3 patent) OR 9486361 OR (361 w/3 patent) OR 11389328 OR (328 w/3 patent) OR 7909789 or (789 w/3 patent)) W/10 valuation
- (11475523 OR (523 w/3 (application or appn or app))) w/10 (purchase OR buy OR sell OR sale OR acquire OR license)
- (Badawi OR (Sight Sciences OR Site Sciences OR Sight Science OR Site Science)) w/5 (patent or application or portfolio)
- (patent W/3 infring*) AND (policy OR procedure OR manual)
- (Schlemm or Schlemm's) w/5 (surface or area or volume or diameter or radius or circumference or "cross-section" or cross section or "cross-sectional" or cross sectional)
- Hydrus AND (10314742 OR (742 w/3 patent) OR 8287482 OR (482 w/3 patent) OR 9370443 OR (443 w/3 patent) OR 9486361 OR (361 w/3 patent) OR 11389328 OR (328 w/3 patent) OR 7909789 or (789 w/3 patent)) AND (alter OR change OR update or avoid or design around)
- Hydrus AND Omni AND market AND (stud* OR report OR compet*)
- Hydrus W/10 (viscodilation OR visco* or OVD or hyaluronate or hyaluronic or HEALON or provisc) w/10 (Schlemm or Schlemm's)
- Hydrus W/5 (flow w/3 (aqueous or humor))
- Hydrus W/5 compet* AND (stud* OR report)
- Hydrus W/5 market
- Badawi
- 11/475,523 OR 11/475523 OR 11475523 OR (523 w/3 (application or appn or app))
- 2007/0298068 OR 20070298068 OR (068 w/3 publication OR pub)
- (Roeder or Shay or Glenn) and patent and (Mika or Mayer or Mofo or Paul or Badawi or Westwood or Ciotti)
- ((30 OR 50) w/1 (% OR percent)) w/ 20 (cylinder OR tubular)) w/50 (area or surface or open or contact or mm2 or square* or mm3 or "cubic mm")
- (arc* or Arcuate) w/10 cylinder
- (1/1/2021-present) Hydrus and (Omni w/25 ("market share" or win or loss or compet* or account or promot* or dilat* or visco* or partner or canaloplasty))
- ((Sight Science* OR Site Science* OR Sight OR Westwood OR Badawi) OR (Arnold w/3 Porter) OR (Shay w/3 Glenn) OR (Jim w/3 Shay) OR (John w/3 Ulin) OR (John w/3 Nilsson) OR (Deb* w/3 Fishman) OR (Matt* w/3 Wolf) OR (Nicholas w/3 Nyemah) OR (Paul w/3 Margulies) OR (Ken* w/3 Galt)) AND (infring* OR "intellectual property" OR IP OR landscape OR (freedom w/3 operate) OR FTO OR diligence)
- (Hydrus and visco*) W/50 (gauge or needle or viscocanalostomy or streamlin* or butter or canaloplasty or 66174)

- (12/695,053 OR 12/695053 OR 12695053 OR (053 w/3 app*) OR 2010/0191329 OR (329 w/3 pub*) OR 13/025,112 OR 13/025112 OR 13025112 OR (112 w/3 app*) OR 2011/0130831 OR (831 w/3 pub*) OR 13/445,816 OR 13/445816 OR 13445816 OR (816 w/3 app*) OR 2012/0197176 OR (176 w/3 pub*) OR 15/182,165 OR 15/182165 OR 15182165 OR (165 w/3 app*) OR 2016/0287440 OR (440 w/3 pub*) OR 16/413,466 OR 16/413466 OR 16413466 OR (466 w/3 app*) OR 2020/0038243 OR (243 w/3 pub*) and (patent or Badawi or sight or site)) AND (infring* OR "intellectual property" OR IP OR landscape OR (freedom w/3 operate) OR FTO OR diligence)

Lauren Strosnick
Direct: +1 650 843 5065

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Wednesday, June 28, 2023 12:33 PM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Teng, Austin C. <austin.teng@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Lauren,

The document with the missing video that I mentioned on the meet-and-confer is SGHT0161937.

Noah Frank

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From: Strosnick, Lauren <lStrosnick@cooley.com>
Sent: Wednesday, June 28, 2023 1:59 PM
To: Frank, Noah S. <noah.frank@kirkland.com>; Teng, Austin C. <austin.teng@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

Yesterday, Dave Van Meter testified that he had a laptop at Ivantis that he handed over to the company in February 2022. He was almost certain that there were emails and documents on that laptop that preceded 2016. On today's meet-and-confer, please also be prepared to confirm that you searched this laptop for responsive documents, as well as any laptops of other Ivantis employees that left after the acquisition.

Thanks,
Lauren

Lauren Strosnick
Direct: +1 650 843 5065

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Wednesday, June 28, 2023 8:38 AM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Teng, Austin C. <austin.teng@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Lauren,

We can use this dial-in.

Join Zoom Meeting
https://kirkland.zoom.us/j/97040129306?pwd=MDNrZUxMQjM5aE83aVdRK3hjczk2dz09

Meeting ID: 970 4012 9306
Passcode: 346612
One tap mobile
+16465588656,,97040129306#,,,,,,0#,,346612# US (New York)
+16469313860,,97040129306#,,,,,,0#,,346612# US

Noah Frank

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noah.frank@kirkland.com

From: Strosnick, Lauren <lStrosnick@cooley.com>
Sent: Tuesday, June 27, 2023 6:47 PM

To: Frank, Noah S. <noah.frank@kirkland.com>; Teng, Austin C. <austin.teng@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

We are available to meet-and-confer on this issue, and the issues identified in our email yesterday (attached), at 3pm ET tomorrow. Please circulate a dial-in. We expect a decision-maker and local counsel to be present.

Thanks,
Lauren

Lauren Strosnick
Direct: +1 650 843 5065

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Tuesday, June 27, 2023 12:20 PM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Teng, Austin C. <austin.teng@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Lauren,

The fact that Sight is spending resources combing through Defendants' production rather than attempting to rectify its own production deficiencies is disappointing. Sight should be able to work with its vendor to identify and produce all missing attachments. Nevertheless, please confirm you are available to meet and confer on this issue tomorrow at 3 pm eastern.

Regards,

Noah Frank

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F +1 202 389 5200

noah.frank@kirkland.com

From: Strosnick, Lauren <lStrosnick@cooley.com>
Sent: Monday, June 26, 2023 7:23 PM
To: Teng, Austin C. <austin.teng@kirkland.com>; Frank, Noah S. <noah.frank@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

As previously explained, Sight's collection, search, review, and production of ESI in this case were conducted in full accordance with the Court's ESI Order (D.I. 49). Contrary to your unsupported assertion, Sight is not "obligated to produce the complete thread, including any attachments referenced throughout[,]" for any email it has produced. Neither the Delaware Default ESI Standard nor the Court's ESI Order requires a focus on email threads; rather, the ESI process involves collecting documents from disclosed custodial and non-custodial sources, running search terms provided by each party, reviewing the results, and producing the full ***family*** of any responsive document (see D.I. 49, para 4.e). These are precisely the steps that Sight undertook. Because this process does not require a focus on email threads, it is not surprising that Sight's application of its own keywords, Defendants' proposed and subsequently narrowed keywords, and human review would result in some portions of an email thread being pulled into the review and others not.

In fixating on email threads, Defendants are fabricating a deficiency where none exists. However, to the extent Defendants insist on raising this issue to the Court and succeed in obtaining relief, Sight intends to bring similar "deficiencies" in Defendants' production to the Court's attention to illustrate that Defendants are improperly attempting to retroactively change the rules for discovery—and that if they are successful, Defendants would also have "deficiencies" to address. Our e-discovery team began a manual review of your production this weekend, and has already identified a substantial number of documents that have no attachment but appear to mention an attachment earlier in the thread.

As noted, we are reviewing the documents you identified (SGHT0030283, SGHT0030410, SGHT0030936, SGHT0031063, SGHT0130538, SGHT0160500) and will supplement our production as appropriate. We remain willing to meet and confer regarding a reasonable number of additional attachments you believe may be responsive that have not been produced, to the extent additional requests are made in a reasonable time frame.

Lastly, we do not agree to adding this issue as an amendment to your 6/23 joint motion for teleconference, as the parties are still conferring about it. We will email you separately about a number of other outstanding discovery issues requiring resolution, and propose times for the parties to confer tomorrow.

Thanks,
Lauren

Lauren Strosnick
Direct: +1 650 843 5065

From: Teng, Austin C. <austin.teng@kirkland.com>
Sent: Friday, June 23, 2023 8:10 PM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Frank, Noah S. <noah.frank@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>; Wood, Alissa <amwood@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Counsel,

Thank you for your time on today's meet and confer. Based on our call, we understand that not all of Sight's emails within a produced email thread were consistently marked as responsive, and as a result, not all attachments referenced throughout the thread have necessarily been produced.

For any email Sight has produced, Sight is obligated to produce the compete thread, including any attachments referenced throughout. The missing information does not appear on your privilege log, and therefore there is no valid reason for withholding the missing emails and attachments. Rule 34(a)(1)(A) requires the production of designated ESI, and nothing in the Discovery Order excuses the parties from having to produce all of the attachments associated with responsive email threads. Your argument regarding the definition of "Family" is beside the point. While the Discovery Order permits deduplication at the "Family level," the Producing Party is still required to produce at least "a single copy of responsive Duplicate ESI." D.I. 49 § 4(d). And the Discovery Order clearly favors production of complete sets of information. *See, e.g.*, D.I. 49 § 4(e) ("Unless documents contain solely Privileged Information, parties will produce complete Document Families where any portion of the Family contains relevant information.").

While you have stated that you do not believe the attachment issue is widespread, we did a quick check following our call and identified as many as 400 emails that reference attachments earlier in the thread. It is unreasonable to expect Defendants to scour your production for missing information when Sight maintains the information in a structured format, and it is easily within your vendor's capabilities to identify all unproduced emails associated with the emails you did produce. There is no undue burden associated with producing the missing information. Your vendor can easily identify the associated emails and attachments and produce them. There is no need to re-review for relevance given your production of an email thread concedes the relevance and responsiveness of the associated emails.

We have notified you repeatedly about the missing attachments since April of this year and have attempted to resolve this without need for court intervention. *See* 4/21/2023 J. Bova Letter at 2; 4/28/2023 J. Bova e-mail; 5/10/2023 J. Bova Letter at 6; 5/26/2023 A. Teng e-mail; 6/12/2023 S. Dirks e-mail. Defendants have also identified examples of the issue as a courtesy. *See, e.g.,* SGHT0030283, SGHT0030410, SGHT0030936, SGHT0031063, SGHT0130538, SGHT0160500. Your offer to continue evaluate any claims of missing attachments on a case-by-case basis is not workable given the late stage of discovery. Therefore, as we discussed on the call, the parties are at impasse with respect to Sight's withholding of email attachments. Attached is an amended joint motion for teleconference. Please let us know if you have any edits so we can get this on file.

We will follow up regarding the items we discussed today from your June 21 email.

Best regards,
Austin

Austin Teng

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austin.teng@kirkland.com

From: Strosnick, Lauren <lStrosnick@cooley.com>
Sent: Friday, June 23, 2023 11:19 AM
To: Frank, Noah S. <noah.frank@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>; Mecham, Ross D <rmecham@cooley.com>; Wood, Alissa <amwood@cooley.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

We are available to meet-and-confer regarding this issue at 5pm ET today. If that works, please send a dial-in. For clarity, we have applied the definition of "family" set forth in the parties' ESI Order – "a group of documents that are maintained as a single unit in the ordinary course of business (*e.g.*, an email and its attachments)." D.I. 49, ¶ 3.b. Contrary to your assertions, an attachment is only part of the document family when its parent document is the last-in-time (LIT) email in the email chain. Your concerns thus remain unfounded. Our e-discovery attorney assigned to this case will join the call to assist with any technical questions.

Please also be prepared to discuss the deficiencies in Defendants' document productions summarized in our attached email from 6/21.

Thanks,
Lauren

Lauren Strosnick
Direct: +1 650 843 5065

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Thursday, June 22, 2023 11:51 AM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Lauren,

Far from being "unfounded," our concerns are evident based on both the deficiencies we have identified, as well as your response, which calls into question the "reasonableness" of Sight's document collection, review, and production. From your email, it appears that Sight believes it can withhold responsive documents from within a family simply because they were not attached to the latest-in-time email. It is also unclear what definition of "family" Sight has been using to collect and review documents.

While Sight has explained what it did to rectify this particular instance, it has not explained why this occurred in the first place. Nor has Sight explained whether it even investigated the cause of this issue. We are available to meet and confer today at 1 pm pacific. Please also be prepared to discuss the missing email response from Paul Badawi on 1/13/2016 that I raised yesterday.

Regards,

Noah Frank

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noah.frank@kirkland.com

From: Strosnick, Lauren <lStrosnick@cooley.com>
Sent: Thursday, June 22, 2023 9:55 AM
To: Frank, Noah S. <noah.frank@kirkland.com>; Rhyu, Michelle <RHYUMS@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

Your concerns regarding alleged "missing attachments" are unfounded. As an initial matter, your description of these documents as having "missing attachments" is a misnomer – the two documents you initially identified are not in fact missing attachments; it is clear from the face of each document that there is no attachment to the last-in-time email. The same is true for the six additional documents you identified on 6/20. Instead, we understand your concern to be about earlier emails in the chain that reference attachments being sent. We therefore searched Sight's documents for the emails referencing attachments in SGHT0031048 and SGHT0031051, and located some or all of the attachments that we will produce by tomorrow. Specifically, here are the steps we took with respect to these two documents:

- We identified that the previous emails referencing attachments were all sent from the paul@sightsciences.com address;
- We searched previously-collected ESI as well as original sources in an effort to locate these messages as the last-in-time sent versions including the attachments;
- We also searched other contemporaneous messages, and identified communications with Stephen Pons that reflect Paul Badawi as an intermediary passing along the attachments;

- We identified contemporaneous standalone documents or messages from Stephen Pons that include attachments corresponding to the documents referenced in the original threads, and will produce those documents this week.

We will undertake a similar investigation for the six additional documents you identified yesterday.

Sight rejects your unfounded allegations regarding the completeness of its production. Sight has undertaken a reasonable collection, review, and production of ESI (including email) based on responsiveness to the issues in this case and Defendants' requests for production, and we have investigated your follow-up questions in good faith. Sight has produced families associated with responsive documents, but the obligation to produce families does not include locating referenced attachments that are not part of those families. While we are willing to perform a reasonable number of searches for specific attachments that you identify, there is no requirement or agreement in this case for the parties to search for attachments referenced in emails that are not part of responsive families.

We are happy to meet and confer to discuss this issue further as needed.

Thanks,
Lauren

Lauren Strosnick
Direct: +1 650 843 5065

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Wednesday, June 21, 2023 5:29 PM
To: Rhyu, Michelle <RHYUMS@cooley.com>; Strosnick, Lauren <lStrosnick@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Michelle,

Contrary to your assertion, spreadsheets in Sight's production indicate otherwise. For example, row 16887 in SGHT0162043 identifies the existence of an email response from Paul Badawi on 1/13/2016 (not produced) to the email dated 12/30/2015 (SGHT0032220). We remain seriously concerned about Sight's process to collect and produce documents in this case. Please confirm that, other than this missing email, you have produced complete families for all responsive emails or explain Sight's rationale for not doing so. At a minimum, by tomorrow, please produce the aforementioned email or explain the discrepancy.

By tomorrow, please also respond to our concerns identified below regarding missing attachments. If this issue is not resolved by tomorrow we intend to raise it with the Court in our motion for teleconference.

Regards,

Noah Frank

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noah.frank@kirkland.com

From: Rhyu, Michelle <RHYUMS@cooley.com>
Sent: Wednesday, June 21, 2023 3:07 PM
To: Frank, Noah S. <noah.frank@kirkland.com>; Strosnick, Lauren <lStrosnick@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Noah,
Regarding the Sight email dated 12/30/2015 (SGHT0032220), we have investigated, and you have received the complete thread of that email. Mr. Badawi did not respond to that email. Other team members will get back to you on the status of the investigation about the purported missing attachments.

Michelle

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Wednesday, June 21, 2023 1:49 PM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; Rhyu, Michelle <RHYUMS@cooley.com>; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>
Subject: RE: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

[External]

Counsel,

I have not received a response to the below email. Please provide your availability to meet and confer regarding this issue today.

Regards,

Noah Frank

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F +1 202 389 5200

noah.frank@kirkland.com

From: Frank, Noah S. <noah.frank@kirkland.com>
Sent: Tuesday, June 20, 2023 7:47 AM
To: Strosnick, Lauren <lStrosnick@cooley.com>; Merideth, Vicki <vicki.merideth@kirkland.com>; cvilloslada@ycst.com; Armon, Orion <oarmon@cooley.com>; Gibbs, Tracy <tgibbs@cooley.com>; Wood, Alissa <amwood@cooley.com>; z/Sight Sciences Ivantis <zSightSciencesIvantis@cooley.com>; Murdter, David <dmurdter@cooley.com>; Douglas, Jeannine <jdouglas@cooley.com>; mgassaway@ycst.com; Rhyu, Michelle <RHYUMS@cooley.com>; thallowell@ycst.com; *jhiggins@ycst.com <jhiggins@ycst.com>; *msharp@ycst.com <msharp@ycst.com>; Vanderwall, Cameron C. <cvanderwall@cooley.com>
Cc: SKIvantis@shawkeller.com; #Alcon-SightSciences <Alcon-SightSciences@kirkland.com>
Subject: C.A. No. 21-1217-GBW-SRF Sight Sciences, Inc. v. Ivantis, Inc. et al. - Document Production Deficiencies

Counsel,

Defendants have for months repeatedly asked Sight to produce all missing attachments from its productions. *See* 4/21/2023 J. Bova Letter at 2; 4/28/2023 J. Bova e-mail; 5/10/2023 J. Bova Letter at 6; 5/26/2023 A. Teng e-mail; 6/12/2023 S. Dirks e-mail. Despite your assertions to the contrary, it is not Defendants' burden to locate all missing attachments in Sight's deficient production; Defendants identified examples of the issue as a courtesy. Sight's "investigation" of the missing attachments issue, in which Sight merely reviewed the two example documents that reference attachments being sent and "locat[ed] some or all of the attachments," does nothing to resolve Defendants' concerns about the pervasiveness of this issue. To date, Sight still has not (1) explained why these attachments were missing, (2) identified and produced other missing attachments, or (3) confirmed that it investigated whether there are additional missing attachments beyond those identified. Indeed, there are many more examples of missing attachments. *See, e.g.,* SGHT0030283, SGHT0030410, SGHT0030936, SGHT0031063, SGHT0130538, SGHT0160500. Defendants emphasize that this list is merely exemplary and it is not Defendants' obligation to identify each and every missing attachment.

To further illustrate Defendants' concerns, Sight's production contains incomplete email threads. For example, an email dated 12/30/2015 (SGHT0032220) poses a question to Paul Badawi and Sight has not produced any email response. As with the missing attachments above, this is only exemplary and Sight has an obligation to produce complete email threads for responsive emails.

Given Mr. Badawi's upcoming deposition, please confirm by Tuesday, June 20 that Sight will produce the missing email response and attachments already identified by Wednesday, June 21. Please also confirm that Sight will investigate why these issues occurred and whether there are other missing attachments and missing emails from threads, and provide explanations by Wednesday, June 21. Defendants' continual discovery of the incomplete state of Sight's production is highly prejudicial. If Sight does not agree to provide explanations regarding these issues by Wednesday, June 21, please provide your availability to meet and confer that day.

Regards,

Noah Frank

KIRKLAND & ELLIS LLP
200 Clarendon Street, Boston, MA 02116
T +1 617 385 7570
F +1 617 385 7501

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MORPHOSYS AG, Plaintiff, v. JANSSEN BIOTECH, INC., GENMAB US, INC., and GENMAB A/S, Defendants.	)	C. A. No.: 16-221 (LPS) (CJB)

STIPULATION AND ORDER CONCERNING PROTOCOL FOR DISCOVERY OF ELECTRONICALLY STORED INFORMATION AND PAPER DOCUMENTS

The Parties (Plaintiff MorphoSys AG ("MorphoSys"), Defendant Janssen Biotech Inc. ("Janssen") and Defendants Genmab U.S. Inc. and Genmab A/S ("the Genmab Defendants")), hereby agree, subject to the approval of the Court, to the following protocol for production of electronically stored information ("ESI") and paper ("hardcopy") documents. Subject to the local rules, the protective order, and any other applicable rule or order by the Court in this Action, this protocol governs all production in the matter.

IT IS HEREBY ORDERED that:

A. GENERAL AGREEMENTS

1. Ongoing Cooperation Among the Parties.

a. The Parties are aware of the importance the Court places on cooperation and commit to continue to consult and cooperate reasonably as discovery proceeds.

2. Proportionality. The Parties are expected to use reasonable, good faith and proportional efforts to preserve, identify and produce relevant information.[1] This includes identifying appropriate limits to discovery, including limits on custodians, identification of relevant subject matter, time periods for discovery and other parameters to limit and guide preservation and discovery issues.

3. Preservation of Discoverable Information. A party has a common law obligation to take reasonable and proportional steps to preserve discoverable information in the party's possession, custody or control.

a. Absent a showing of good cause by the requesting party, the Parties shall not be required to modify, on a going-forward basis, the procedures used by them in the ordinary course of business to back up and archive data; provided, however, that the Parties shall preserve the non-duplicative discoverable information currently in their possession, custody or control.

b. Non-Discoverable ESI. Consistent with the proportionality standard, the local rules, and any other applicable rule or order by the Court in this Action, and absent a showing of good cause by the requesting party, the categories of ESI identified below, need not be preserved:

i. ESI deleted in the normal course of business before the time a preservation obligation in this matter came into effect;

ii. Backup data files that are maintained in the normal course of business for purposes of disaster recovery, including (but not limited to) backup tapes, disks,

[1] Information can originate in any form, including ESI and paper, and is not limited to information created or stored electronically.

SAN, and other forms of media, and that are substantially duplicative of data that are more accessible elsewhere;

iii. Deleted, "slack," fragmented, or unallocated data only accessible by forensics;

iv. Random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system;

v. On-line access data such as (without limitation) temporary internet files, history files, cache files, and cookies;

vi. Data in metadata fields frequently updated automatically, such as last-opened or last-printed dates;

vii. Electronic data (e.g., call logs, email, calendars, contact data, notes, and text messages) sent to or from on mobile devices (e.g., iPhone, Android, and Blackberry devices), provided that a copy of all such electronic data is routinely saved elsewhere (such as on a server, laptop, desktop computer, or 'cloud' storage);

viii. Voicemail, including Telephone or VOIP voice messages;

ix. Text messages and instant messages that are not retained in the ordinary course of business;

x. Server, system, network, or software application logs;

xi. Data remaining from systems no longer in use that is unintelligible on the systems in use;

xii. Electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report;

xiii. Files included on the National Institute of Standards and Technology (NIST) List (http://www.nsrl.nist.gov/);

xiv. Structural files not material to individual file contents (e.g. .CSS, .XSL, .XML, .DTD, etc.);

xv. Operating System files that do not store user-created content (e.g. CAT, DLL, DMP, EXE, FON, PNF, OPS, SYS etc.);

xvi. Application source code, configuration, and other similar files necessary for the function of an application that do not store user-created content during ordinary use (E.g. BAK, BIN, CFG, DBF, DAT, JS, JSON, JAR, LUA, MSB, RES, WINNT, YTR etc.)

4. Reasonable Discovery Limits:

a. Post-ESI Stipulation. The Parties shall not be obligated to collect or produce ESI created after [**MorphoSys's Proposal**: August 31, 2016, **Defendants' Proposal:** April 4, 2016] unless agreed to by the Parties or ordered by the Court.

b. Discoverable Custodians and Non-Custodial Data Sources.

MorphoSys's Proposal: Consistent with the Court's Default Standard for Discovery (3(a-b)) MorphoSys shall identify ten custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information. Janssen shall likewise identify ten custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information. In the interest of efficiency and compromise, MorphoSys agrees that Genmab Defendants (Genmab US, Inc. and Genmab A/S) shall collectively

identify ten custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information.

Defendants' Proposal: MorphoSys shall identify ten custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information. Janssen shall identify nine custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information. Genmab Defendants (Genmab US, Inc. and Genmab A/S) shall collectively identify six custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information.

c. The Parties Agree that the Section 3 Disclosures (including Custodians (3a), Non-custodial data sources (3b), items subject to Notice (3c)) and Search Terms shall be exchanged no later than October 12, 2016. The list of the non-custodial data sources are to be disclosed at that time that are most likely to contain non-duplicative discoverable information for preservation and production consideration, from the most likely to the least likely. These central data sources and custodial sources are to be used for applying search terms, and producing responsive information to the opposing party.

d. On-Site Inspections of ESI. On-site inspections shall not be permitted absent a demonstration by the requesting party of specific need and good cause or upon agreement by the Parties. *See* Default Standard for Discovery at 5(b).

e. Disaster-Recovery Backup Data. Absent a Party's specific written notice for good cause, no Party shall be required to modify or suspend procedures, including rotation of backup media, used in the normal course of business to back up data and systems for disaster recovery purposes. Absent a showing of good cause, such backup media shall be considered to be not reasonably accessible.

5. No Designation of Discovery Requests.

a. Productions of hardcopy documents and ESI in the reasonably usable form set out in this protocol, including Attachment A, need not be organized and labeled to correspond to the categories in the requests.

6. Privileged Material.

a. The Parties agree to exchange privilege logs and to negotiate a mutually agreeable deadline for such exchange. The Parties agree to meet and confer with respect to the required contents of the privilege logs. The Parties further agree that privileged documents created on or after the date of the complaint shall not be included in privilege logs, except to the extent otherwise agreed by the Parties or ordered by the Court. *See* Default Standard for Discovery at 1(d)(ii) ("With respect to information generated after the filing of the complaint, parties are not required to include any such information in privilege logs.").

b. Document hold letters are privileged. *See* Default Standard for Discovery at 1(d)(iii).

c. Documents involving litigation counsel shall not be included in privilege logs, except to the extent otherwise agreed by the Parties or ordered by the Court.

d. The unintentional production of any material constituting or containing information that is privileged or protected from discovery, including but not limited to any attorney-client privilege, work product privilege, joint defense privilege, or settlement privilege, or any other applicable privilege or immunity from discovery, shall be governed by provisions contained in the Protective Order entered in this action, and any other applicable rule or Court order.

7. Electronic Service. The Parties agree to accept service by electronic means under Fed. R. Civ. P. 5(b)(2)(E).

B. ELECTRONICALLY STORED INFORMATION

1. Production in Reasonably Usable Form

a. The Parties shall produce electronically stored information in reasonably usable form. Except as stated in paragraphs B.2 and B.3 below or as agreed hereafter by the Parties, such reasonably usable form shall be the single-page TIFF-image format with extracted or OCR text and associated metadata set out in Attachment A ("TIFF-*Plus* format"), which is incorporated in full in this protocol. If the Receiving Party, for good cause explained in the request, seeks production in native format of specifically identified ESI produced originally in TIFF-*Plus* format, the Producing Party shall respond reasonably and in good faith to any such request. Procedures for production of a native file in response to any such request are set out in Attachment A, Paragraph A.15.b.

b. Each Party may make requests, for good cause, for production of specifically identified documents in color.

2. Electronic Spreadsheets, Presentations, Desktop Databases, and Multimedia Files.

a. Electronic spreadsheets (e.g., Excel), desktop databases (e.g., Access), and audio/video multimedia files that have been identified as producible shall be produced in native format as described in Paragraph A.15.a of Attachment A. Electronic presentations (e.g., PowerPoint) may be produced in native or imaged form. The Parties shall not unreasonably refuse a good faith request for the production in native form of a document produced in imaged form.

3. Redactions.

a. **MorphoSys's Proposal**: Documents shall not be redacted on the basis of confidentiality or non-responsiveness, but protected from dissemination to the opposing Party through the provisions of the Protective Order.

b. **Defendants' Proposal**: The Producing Party may redact from any TIFF image, metadata field, or native file material that is protected from disclosure by applicable privilege or immunity or that is governed by any applicable privacy law or regulation. Redactions of non-responsive information considered to be, for example, commercially sensitive, forward-looking or proprietary business or research and development information are permissible, but to the extent that a party asserts that such redacted material is necessary to ascertain the context of unredacted material, the Parties agree to meet and confer regarding the production of a version of the TIFF image, metadata field, or native file that shows such material. The Parties agree that they will negotiate in good faith and will not unreasonably refuse to uncover redacted material.

c. Each redaction in a TIFF-image shall be indicated clearly.

d. For native files requiring redaction, redacted text shall be replaced with the term "Redacted" when feasible, and the Producing Party either shall produce the redacted file in the reasonably usable form set out in Paragraph B(1)(a) or shall produce the redacted copy in

native format. If redaction of information in a native spreadsheet should require elimination of any embedded formula relevant to the claims or defenses, the Producing Party shall so inform the Receiving Party in writing at the time of production.

e. If the Receiving Party should challenge any redaction, the Parties shall abide by the terms of the Protective Order, and any other applicable rule or Court order, and shall handle any such challenge in accordance with those terms.

4. Use of Search Term Filters.

a. The parties agree to disclose the search terms to be used to search custodial and non-custodial data sources on October 12, 2016.

b. **MorphoSys's Proposal**: Consistent with the Court's Default Standard for Discovery (Including Discovery of ESI), absent a showing of good cause, a requesting party may request no more than 10 additional terms to be used in connection with the electronic search on or before October 17, 2016. Focused terms, rather than over-broad terms (e.g ., product and company names), shall be employed . The producing party shall search (i) the non-custodial data sources identified in accordance with paragraph 3(b); and (ii) emails and other ESI maintained by the custodians identified in accordance with paragraph 3(a).

c. **Defendants' Proposal**: After the Producing Party has first disclosed its search term filters, and only if any other party believes in good faith that use of the disclosed search term filters would result in deficiencies in production, the Parties will work collaboratively on any revisions to such filters (such as requesting the use of no more than 10 additional search terms). Any proposed search term filters shall be narrowly tailored to particular claims and defenses. Focused terms, rather than over-broad terms (e.g., product and company names), shall be employed.

d. The Parties agree that the Producing Party shall retain the sole right and responsibility to manage and control searches of its data files.

i. The fact that any electronic file has been identified in agreed-upon searches shall not prevent any Party from withholding such file from production on the grounds that the file is not responsive or protected from disclosure by applicable privilege or immunity.

e. Nothing in this section shall limit a Party's right reasonably to seek agreement from the other Parties or a court ruling to modify previously agreed-upon search terms and phrases.

5. Email Threading.

a. Email threads are email communications that contain prior or lesser-included email communications that also may exist separately in the Party's electronic document collection. A most-inclusive email is one that contains unique content and all of the lesser-included emails, including attachments, for that branch of the email thread. The Parties agree that removal of lesser-included versions from potential production will reduce all Parties' costs of document review, production, and litigation-support hosting. Accordingly, each Party may produce or list on any required privilege log only the most inclusive email threads. To the extent a lesser-included email contains a nontrivial attachment not otherwise produced with the most-inclusive email, the Parties will produce or list on any required privilege log the lesser-included email and any accompanying attachment to the extent it otherwise would have been subject to production.

b. Following production of most inclusive email threads, and for good cause, a Receiving Party may make reasonable requests, with respect to most-inclusive email threads particularly identified in the requests, for metadata associated with individual lesser-included

emails. The Producing Party shall cooperate reasonably in responding to any such requests if the requested lesser-included emails otherwise would have been subject to production.

6. Avoidance of Duplicate Production

a. "Duplicate ESI" means files that are exact duplicates based on the files' MD5 or SHA-1 and/or SHA-180 hash values. The Producing Party need produce only a single copy of responsive Duplicate ESI. A Producing Party shall take reasonable steps to de-duplicate ESI globally (i.e., both within a particular custodian's files and across all custodians), and agrees to use industry standard deduplication procedures and programs. Entire document families may constitute Duplicate ESI. De-duplication shall not break apart families. Attachments to any mail may not be withheld from production on the basis of deduplication, even if the attachment is an exact duplicate of a document produced elsewhere in the production. When the same Duplicate ESI exists in the files of multiple custodians, those persons shall be listed in the OTHER_CUSTODIANS field identified in Paragraph A.14(c) of Attachment A.

b. If and when the Producing Party makes supplemental productions following an initial production, that Party also shall provide with each supplemental production an overlay file to allow the Receiving Party to update the OTHER_CUSTODIANS field. The overlay file shall include both all custodians listed in the OTHER_CUSTODIANS field in prior productions and any custodians newly identified in the current supplemental production.

C. DOCUMENTS THAT EXIST ONLY IN HARDCOPY (PAPER) FORM

A Party may produce documents that exist in the normal course of business only in hardcopy form either (a) in their original hardcopy form or (b) scanned and produced, redacted as necessary, in accordance with the procedures set out in Attachment A.

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

DATED:_____ _____
Attorneys for Plaintiff MorphoSys AG

DATED:_____ _____
Attorneys for Defendant Janssen Biotech, Inc.

DATED:_____ _____
Attorneys for Defendant Genmab U.S., Inc.

DATED:_____ _____
Attorneys for Defendant Genmab A/S

PURSUANT TO STIPULATION, IT IS SO ORDERED.

DATED:_____ _____
LEONARD P. STARK
Chief United States District Judge

ATTACHMENT A
TECHNICAL SPECIFICATIONS

A.1 Image Files. Files produced in *.tif format will be single page black and white *.tif images at 300 DPI, Group IV compression. To the extent possible, original orientation will be maintained (i.e., portrait-to-portrait and landscape-to-landscape). Each *.tif image will be assigned a unique name matching the production number of the corresponding page. Such files will be grouped in folders of no more than 1,000 *.tif files each unless necessary to prevent a file from splitting across folders. Files will not be split across folders and separate folders will not be created for each file. Production ("Bates") numbers shall be endorsed on the lower right corner of all images. This number shall be a unique, consistently formatted identifier that will:

a. be consistent across the production;

b. contain no special characters; and

c. be numerically sequential within a given file.

Bates numbers should be a combination of an alpha prefix along with an 8 digit number (e.g. ABC00000001). The number of digits in the numeric portion of the Bates number format should not change in subsequent productions. Confidentiality designations, if any, will be endorsed on the lower left corner of all images and shall not obscure any portion of the original file.

A.2 File Text. Except where ESI contains text that has been redacted under assertion of privilege or other permissible protection from disclosure, full extracted text will be provided in the format of a single *.txt file for each file (i.e., not one *.txt file per *.tif image). Where ESI contains text that has been redacted under assertion of privilege or other protection from disclosure, the redacted *.tif image will be OCR'd and file-level OCR text will be provided in lieu of extracted text. Searchable text will be produced as file-level multi-page UTF-8 text files with the text file named to match the beginning production number of the file. The full path of

the text file must be provided in the *.dat data load file. The text file shall include interlineated image keys/bates numbers sufficient to show, for all TIFF-image pages, the bates-numbered page of the associated text.

A.3 Word Processing Files. Word processing files, including without limitation Microsoft Word files (*.doc and *.docx), will be produced in the above format with tracked changes, comments, and hidden text showing.

A.4 Presentation Files. To the extent that presentation files, including without limitation Microsoft PowerPoint files (*.ppt and *.pptx), are produced in *.tif image format, such *.tif images will display comments, hidden slides, speakers' notes, and similar data in such files.

A.5 Spreadsheet or Worksheet Files. To the extent that spreadsheet files, including without limitation Microsoft Excel files (*.xls or *.xlsx), are produced in *.tif image format, such *.tif images will display hidden rows, columns, and worksheets, if any, in such files.

A.6 Parent-Child Relationships. Parent-child relationships (e.g., the associations between emails and their attachments) will be preserved. Email and other ESI attachments will be produced as independent files immediately following the parent email or ESI record. Parent-child relationships will be identified in the data load file pursuant to paragraph A.14 below.

A.7 Dynamic Fields. Files containing dynamic fields such as file names, dates, and times will be produced showing the field type (e.g., "[FILENAME]" or "[AUTODATE]"), rather than the values for such fields existing at the time the file is processed.

A.8 English Language. To the extent any data exists in more than one language, the data will be produced in English, if available. If no English version of a file is available, the Producing Party shall not have an obligation to produce an English translation of the data.

A.9 Embedded Objects. Some Microsoft Office and .RTF files may contain embedded objects. Such objects typically are the following file types: Microsoft Excel, Word, PowerPoint, Project, Outlook, and Access; and PDF. Subject to claims of privilege and immunity, as applicable, objects with those identified file types shall be extracted as separate files and shall be produced as attachments to the file in which they were embedded.

A.10 Compressed Files. Compressed file types (i.e., .CAB, .GZ, .TAR. .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual files.

A.11 Encrypted Files. The Producing Party will take reasonable steps, prior to production, to unencrypt any discoverable electronically stored information that exists in encrypted format (e.g., because of password-protection) and that can be reasonably unencrypted. What constitutes a reasonable step shall be governed by the Federal Rules of Civil Procedure and the Parties agree to meet and confer concerning matters of encryption and to attempt to amicably resolve any dispute related thereto, and to move before the Court as necessary.

A.12 Scanned Hardcopy Documents.

a. In scanning hardcopy documents, multiple distinct documents should not be merged into a single record, and single documents should not be split into multiple records (i.e., hard copy documents should be logically or physically unitized).

b. If the Producing Party produces hard copy documents in scanned form, that Party agrees to provide OCR text for scanned images of hard copy documents. OCR should be performed on a document level and provided in document-level *.txt files named to match the production number of the first page of the document to which the OCR text corresponds. OCR text should not be delivered in the data load file or any other delimited text file. Alternatively,

the text of ESI may be provided as separately fielded data within the Concordance delimited file as described herein.

c. In the case of an organized compilation of separate hardcopy documents—for example, a binder containing several separate documents behind numbered tabs—the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the family fields set out below.

A.13 Production Numbering.

a. In following the requirements of Paragraph A.1, the Producing Party shall take reasonable steps to ensure that attachments to documents or electronic files are assigned production numbers that directly follow the production numbers on the documents or files to which they were attached. If a production number or set of production numbers is skipped, the skipped number or set of numbers will be noted. In addition, wherever possible, each *.tif image will have its assigned production number electronically "burned" onto the image.

A.14 Data and Image Load Files.

a. Load Files Required. Unless otherwise agreed, each production will include a data load file in Concordance (*.dat) format and an image load file in Opticon (*.opt) format.

b. Load File Formats.

i. Load file names should contain the volume name of the production media. Additional descriptive information may be provided after the volume name. For example, both ABC001.dat or ABC001_metadata.dat would be acceptable.

ii. Unless other delimiters are specified, any fielded data provided in a load file should use Concordance default delimiters. Semicolon (;) should be used as multi-entry separator.

iii. Any delimited text file containing fielded data should contain in the first line a list of the fields provided in the order in which they are organized in the file.

c. Fields to be Included in Data Load File. For all documents or electronic files produced, the following metadata fields for each document or electronic file, if available at the time of collection and processing and unless such metadata fields are protected from disclosure by attorney-client privilege or work-product immunity or otherwise prohibited from disclosure by law or regulation, will be provided in the data load file pursuant to subparagraph (a), above, except to the extent that a document or electronic file has been produced with redactions. The term "Scanned Docs" refers to documents that are in hard copy form at the time of collection and have been scanned into *.tif images. The term "Email and E-Docs" refers to files that are in electronic form at the time of their collection, irrespective of the form (TIFF-Plus or native format) in which they are produced.

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
PRODBEG [Key Value]	ABC00000001	Yes	Yes	Beginning production number
PRODEND	ABC00000008	Yes	Yes	Ending production number
PRODBEGATT	ABC00000009	Yes	Yes	Beginning production number of parent in a family
PRODENDATT	ABC00001005	Yes	Yes	Ending production number of last page of the last attachment in a family
CUSTODIAN	Smith, John	Yes	Yes	Custodian(s) that possessed the document or electronic file—multiple custodians separated by semicolon
OTHER_CUSTODIANS	Doe, Jane; Jones, James	Yes	Yes	When global de-duplication is used, these are custodians whose file has been de-duplicated
NATIVEFILE	Natives\\ \00000001.xls	N/A	Yes	Path and file name for native file on production media
FILEDESC	Microsoft Office 2007 Document	N/A	Yes	Description of the type file for the produced record.
FOLDER	\My Documents\Document1.doc	N/A	Yes	Original source folder for the record produced.
FILENAME	Document1.doc	N/A	Yes	Name of original electronic file as collected.
DOCEXT	DOC	N/A	Yes	File extension for email or e-doc

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
PAGES	2	Yes	Yes	Number of pages in the produced document or electronic file (not applicable to native file productions).
AUTHOR	John Smith	N/A	Yes	Author information as derived from the properties of the document.
DATECREATED	10/09/2005	N/A	Yes	Date that non-email file was created as extracted from file system metadata
DATELASTMOD	10/09/2005	N/A	Yes	Date that non-email file was modified as extracted from file system metadata
SUBJECT	Changes to Access Database	N/A	Yes	"Subject" field extracted from email message or metadata properties of the document
FROM	John Beech	N/A	Yes	"From" field extracted from email message
TO	Janice Birch	N/A	Yes	"To" field extracted from email message
CC	Frank Maple	N/A	Yes	"Cc" or "carbon copy" field extracted from email message
BCC	John Oakwood	N/A	Yes	"Bcc" or "blind carbon copy" field extracted from email message
DATESENT	10/10/2005	N/A	Yes	Sent date of email message (mm/dd/yyyy format)
TIMESENT	10:33 am	N/A	Yes	Sent time of email message, time zone set to GMT
DATERCVD	10/10/2005	N/A	Yes	Received date of email message (mm/dd/yyyyformat)
TIMERCVD	10:33 am	N/A	Yes	Received time of email message, time zone set to GMT
CONFIDENTIALITY	HIGHLY CONFIDENTIAL	Yes	Yes	Text of confidentiality designation, if any
TEXTPATH	Text\\\.txt	Yes	Yes	Path to *.txt file containing extracted or OCR text
PRODVOL	VOL001	Yes	Yes	Name of the Production Volume

A.15 Files Produced in Native Format.

a. For any electronic file produced initially as a native file in accordance with Paragraph B.2 of the Protocol above, the file shall be given a file name consisting of a unique Bates number and, as applicable, a suitable confidentiality designation; for example, "ABC00000002_Confidential." For each such native file, the production will include a *.tif image slipsheet (i) indicating the production number of the native file, (ii) with respect to any confidential document, setting forth the full confidentiality language applicable to the native file

as set out in the protective order, and (iii) stating "File Provided Natively." To the extent that it is available, the original or redacted file text shall be provided in a file-level multi-page UTF-8 text file with a text path provided in the *.dat file; otherwise the text contained on the slipsheet shall be provided in the *.txt file with the text path provided in the *.dat file.

b. For any electronic file produced in native file format following production of a TIFF-image in accordance with Paragraph B.1, the file shall be given a file name consisting of (i) the Bates number of the first page of the associated TIFF-image and (ii) as applicable, a suitable confidentiality designation. For each such native file, the production will include a new .DAT file (i) indicating the production number of the native file, (ii) identification of the path to the native file, (iii) a field stating "Yes," indicating that the file was produced in both native and TIFF formats, and (iv) linking the metadata associated with the originally produced TIFF image to the newly produced native file."

A.16 Production Media. Unless otherwise agreed, documents and ESI will be produced on optical media (CD/DVD), external hard drive, secure FTP site, or similar electronic format. Such media should have an alphanumeric volume name; if a hard drive contains multiple volumes, each volume should be contained in an appropriately named folder at the root of the drive. Volumes should be numbered consecutively (ABC001, ABC002, etc.). Deliverable media should be labeled with the name of this action, the identity of the producing Party, and the following information: Volume name, production range(s), and date of delivery.

A.17 Encryption of Production Media. To maximize the security of information in transit, any media on which documents or electronic files are produced may be encrypted by the producing Party. In such cases, the producing Party shall transmit the encryption key or password to the requesting Party, under separate cover, contemporaneously with sending the

encrypted media. The receiving Parties in this matter are on notice that certain data produced may originate from custodians in the European Union and the receiving Parties therefore agree to follow the strictest security standards in guarding access to said data.

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FLATFROG LABORATORIES AB, Plaintiff, vs. PROMETHEAN LTD. AND PROMETHEAN INC., Defendants.	C.A. No. 1:19-cv-02246-MN

STIPULATION AND ORDER CONCERNING PROTOCOL FOR DISCOVERY OF ELECTRONICALLY STORED INFORMATION AND PAPER DOCUMENTS

Plaintiff FlatFrog Laboratories AB and Defendants Promethean Ltd. and Promethean Inc. hereby agree, subject to the approval of the Court, to the following protocol for production of electronically stored information ("ESI") and paper ("hardcopy") documents. Subject to the local rules, the protective order, and any other applicable rule or order by the Court in this Action, this protocol governs all production in the matter.

IT IS HEREBY ORDERED that:

A. GENERAL AGREEMENTS

1. Ongoing Cooperation Among the Parties.

a. The Parties are aware of the importance the Court places on cooperation and commit to continue to consult and cooperate reasonably as discovery proceeds.

2. Proportionality. The Parties are expected to use reasonable, good faith and proportional efforts to preserve, identify and produce relevant information.[1] This includes

[1] Information can originate in any form, including ESI and paper, and is not limited to information created or stored electronically.

identifying appropriate limits to discovery, including limits on custodians, identification of relevant subject matter, time periods for discovery and other parameters to limit and guide preservation and discovery issues.

3. Preservation of Discoverable Information. A party has a common law obligation to take reasonable and proportional steps to preserve discoverable information in the party's possession, custody or control.

a. Absent a showing of good cause by the requesting party, the Parties shall not be required to modify, on a going-forward basis, the procedures used by them in the ordinary course of business to back up and archive data; provided, however, that the Parties shall preserve the non-duplicative discoverable information currently in their possession, custody or control.

b. **Non-Discoverable ESI.** Consistent with the proportionality standard, the local rules, and any other applicable rule or order by the Court in this Action, and absent a showing of good cause by the requesting party, the categories of ESI identified below, need not be preserved or collected:

i. ESI deleted in the normal course of business before the time a preservation obligation in this matter came into effect;

ii. Backup data files that are maintained in the normal course of business for purposes of disaster recovery, including (but not limited to) backup tapes, disks, SAN, and other forms of media, and that are substantially duplicative of data that are more accessible elsewhere;

iii. Deleted, “slack,” fragmented, or unallocated data only accessible by forensics;

iv. Random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system;

v. On-line access data such as (without limitation) temporary internet files, history files, cache files, and cookies;

vi. Data in metadata fields frequently updated automatically, such as last-opened or last-printed dates, with the exception of the specific metadata fields identified to exchange as described in Paragraph A.13.c of Attachment A;

vii. Electronic data (e.g., call logs, email, calendars, contact data, notes, and text messages) sent to or from on mobile devices (e.g., iPhone, Android, and Blackberry devices), provided that a copy of all such electronic data is routinely saved elsewhere (such as on a server, laptop, desktop computer, or ‘cloud’ storage);

viii. Voicemail, including Telephone or VOIP voice messages;

ix. Text messages and instant messages (such as Microsoft Teams, Slack, Google Hangouts, Facebook Workplace, etc.);

x. Server, system, network, or software application logs;

xi. Data remaining from systems no longer in use that is unintelligible on the systems in use;

xii. Electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report;

xiii. Files included on the National Institute of Standards and Technology (NIST) List (http://www.nsrl.nist.gov/);

xiv. Structural files not material to individual file contents (e.g. .CSS, .XSL, .XML, .DTD, etc.);

xv. Operating System files that do not store user-created content (e.g. CAT, DLL, DMP, EXE, FON, PNF, OPS, SYS etc.);

xvi. Application source code, configuration, and other similar files necessary for the function of an application that do not store user-created content during ordinary use (E.g. BAK, BIN, CFG, DBF, DAT, JS, JSON, JAR, LUA, MSB, RES, WINNT, YTR etc.)

4. Reasonable Discovery Limits:

a. **Discoverable Custodians and Non-Custodial Data Sources.** Consistent with the Court's Default Standard for Discovery (3(a-b)) Plaintiff shall identify ten custodians most likely to have discoverable information in its possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information. Defendants shall likewise collectively identify ten custodians most likely to have discoverable information in their possession, custody or control, from the most to least likely. The custodians shall be identified by name, title, role in the instant dispute and the subject matter of information.

b. The Parties Agree that the Section 3 Disclosures of Custodians (3a), Non-custodial data sources (3b), and Notice (3c) shall be exchanged no later than **February 26, 2021.** The list of the non-custodial data sources is to be disclosed at that time that are most likely to contain non-duplicative discoverable information for preservation and production consideration, from the most likely to the least likely. These central data sources and custodial sources are to be used for applying search terms, and producing responsive information to the opposing party.

c. **On-Site Inspections of ESI.** On-site inspections shall not be permitted absent a demonstration by the requesting party of specific need and good cause or upon agreement by the Parties. *See* Default Standard for Discovery at 5(b).

d. **Disaster-Recovery Backup Data.** Absent a Party's specific written notice for good cause, no Party shall be required to modify or suspend procedures, including rotation of backup media, used in the normal course of business to back up data and systems for disaster recovery purposes. Absent a showing of good cause, such backup media shall be considered to be not reasonably accessible.

5. No Designation of Discovery Requests.

a. Productions of hardcopy documents and ESI in the reasonably usable form set out in this protocol, including Attachment A, need not be organized and labeled to correspond to the categories in the requests.

6. Privileged Material.

a. The Parties agree to exchange privilege logs and to negotiate a mutually agreeable deadline for such exchange. The Parties agree to meet and confer with respect to the required contents of the privilege logs. The Parties further agree that privileged documents created on or after the date of the complaint shall not be included in privilege logs, except to the extent otherwise agreed by the Parties or ordered by the Court. *See* Default Standard for Discovery at 1(d)(ii) ("With respect to information generated after the filing of the complaint, parties are not required to include any such information in privilege logs.").

b. Document hold letters are privileged. *See* Default Standard for Discovery at 1(d)(iii).

c. Documents involving litigation counsel shall not be included in privilege logs, except to the extent otherwise agreed by the Parties or ordered by the Court.

d. The unintentional production of any material constituting or containing information that is privileged or protected from discovery, including but not limited to any attorney-client privilege, work product privilege, joint defense privilege, or settlement privilege, or any other applicable privilege or immunity from discovery, shall be governed by provisions contained in the Protective Order entered in this action, and any other applicable rule or Court order.

7. Electronic Service. The Parties agree to accept service by electronic means under Fed. R. Civ. P. 5(b)(2)(E).

B. ELECTRONICALLY STORED INFORMATION

1. Production in Reasonably Usable Form

a. The Parties shall produce electronically stored information in reasonably usable form. Except as stated in paragraphs B.2 and B.3 below or as agreed hereafter by the Parties, such reasonably usable form shall be the single-page TIFF-image format with extracted or OCR text and associated metadata set out in Attachment A ("TIFF-*Plus* format"), which is incorporated in full in this protocol. If the Receiving Party, for good cause explained in the request, seeks production in native format of specifically identified ESI produced originally in TIFF-*Plus* format, the Producing Party shall respond reasonably and in good faith to any such request. Procedures for production of a native file in response to any such request are set out in Attachment A, Paragraph A.14.b.

b. Each Party may make requests, for good cause, for production of specifically identified documents in color.

2. Electronic Spreadsheets, Presentations, Desktop Databases, and Multimedia Files.

a. Electronic spreadsheets (e.g., Excel), desktop databases (e.g., Access), and audio/video multimedia files that have been identified as producible shall be produced in native format as described in Paragraph A.14.a of Attachment A. Electronic presentations (e.g., PowerPoint) may be produced in native or imaged form. The Parties shall not unreasonably refuse a good faith request for the production in native form of a document produced in imaged form.

3. Redactions.

a. Each redaction in a TIFF-image shall be indicated clearly.

b. For native files requiring redaction, redacted text shall be replaced with the term "Redacted" when feasible, and the Producing Party either shall produce the redacted file in the reasonably usable form set out in Paragraph B(1)(a) or shall produce the redacted copy in native format. If redaction of information in a native spreadsheet should require elimination of any embedded formula relevant to the claims or defenses, the Producing Party shall so inform the Receiving Party in writing at the time of production.

c. If the Receiving Party should challenge any redaction, the Parties shall abide by the terms of the Protective Order, and any other applicable rule or Court order, and shall handle any such challenge in accordance with those terms.

4. Use of Search Term Filters.

a. The parties agree to disclose the search terms to be used to search custodial and non-custodial data sources and to negotiate a mutually agreeable deadline for such disclosure**.**

b. Consistent with the Court's Default Standard for Discovery (Including Discovery of ESI), absent a showing of good cause, a requesting party may request no more than 10 additional terms to be used in connection with the electronic search on or before a date to be agreed by and between the parties**.** Focused terms, rather than over-broad terms (*e.g.*, product and company names), shall be employed. The producing party shall search (i) the non-custodial data

sources identified in accordance with paragraph 3(b) of the Court's Default Standard for Discovery; and (ii) emails and other ESI maintained by the custodians identified in accordance with paragraph 3(a) of the Court's Default Standard for Discovery.

c. The Parties agree that the Producing Party shall retain the sole right and responsibility to manage and control searches of its data files.

i. The fact that any electronic file has been identified in agreed-upon searches shall not prevent any Party from withholding such file from production on the grounds that the file is not responsive or protected from disclosure by applicable privilege or immunity.

d. Nothing in this section shall limit a Party's right reasonably to seek agreement from the other Parties or a court ruling to modify previously agreed-upon search terms and phrases.

5. Email Threading.

a. Email threads are email communications that contain prior or lesser-included email communications that also may exist separately in the Party's electronic document collection. A most-inclusive email is one that contains unique content and all of the lesser-included emails, including attachments, for that branch of the email thread. The Parties agree that removal of lesser-included versions from potential production will reduce all Parties' costs of document review, production, and litigation-support hosting. Accordingly, each Party may produce or list on any required privilege log only the most inclusive email threads. To the extent a lesser-included email contains a nontrivial attachment not otherwise produced with the most-inclusive email, the Parties will produce or list on any required privilege log the lesser-included email and any accompanying attachment to the extent it otherwise would have been subject to production.

b. Following production of most inclusive email threads, and for good cause, a Receiving Party may make reasonable requests, with respect to most-inclusive email threads

particularly identified in the requests, for metadata associated with individual lesser-included emails. The Producing Party shall cooperate reasonably in responding to any such requests if the requested lesser-included emails otherwise would have been subject to production.

6. Avoidance of Duplicate Production

a. "Duplicate ESI" means files that are exact duplicates based on the files' MD5 or SHA-1 and/or SHA-180 hash values. The Producing Party need produce only a single copy of responsive Duplicate ESI. A Producing Party shall take reasonable steps to de-duplicate ESI globally (i.e., both within a particular custodian's files and across all custodians), and agrees to use industry standard deduplication procedures and programs. Entire document families may constitute Duplicate ESI. De-duplication shall not break apart families. Attachments to any mail may not be withheld from production on the basis of deduplication, even if the attachment is an exact duplicate of a document produced elsewhere in the production. When the same Duplicate ESI exists in the files of multiple custodians, those persons shall be listed in the OTHER_CUSTODIANS field identified in Paragraph A.13(c) of Attachment A.

b. If and when the Producing Party makes supplemental productions following an initial production, that Party also shall provide with each supplemental production an overlay file to allow the Receiving Party to update the OTHER_CUSTODIANS field. The overlay file shall include both all custodians listed in the OTHER_CUSTODIANS field in prior productions and any custodians newly identified in the current supplemental production.

C. DOCUMENTS THAT EXIST ONLY IN HARDCOPY (PAPER) FORM

A Party may produce documents that exist in the normal course of business only in hardcopy form either (a) in their original hardcopy form or (b) scanned and produced, redacted as necessary, in accordance with the procedures set out in Attachment A.

ASHBY GEDDES

/s/ Andrew C. Mayo

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Attorneys for Defendants

SO ORDERED this 19th day of January, 2021.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

ATTACHMENT A
TECHNICAL SPECIFICATIONS

A.1 Image Files. Files produced in *.tif format will be single page black and white *.tif images at 300 DPI, Group IV compression. To the extent possible, original orientation will be maintained (i.e., portrait-to-portrait and landscape-to-landscape). Each *.tif image will be assigned a unique name matching the production number of the corresponding page. Such files will be grouped in folders of no more than 5,000 *.tif files each unless necessary to prevent a file from splitting across folders. Files will not be split across folders and separate folders will not be created for each file. Production ("Bates") numbers shall be endorsed on the lower right corner of all images. This number shall be a unique, consistently formatted identifier that will:

a. be consistent across the production;
b. contain no special characters; and
c. be numerically sequential within a given file.

Bates numbers should be a combination of an alpha prefix along with a 7- or 8- digit number (e.g., ABC1234567 or ABC12345678). The number of digits in the numeric portion of the Bates number format should not change in subsequent productions. Confidentiality designations, if any, will be endorsed on the lower left corner of all images and shall not obscure any portion of the original file.

A.2 File Text. Except where ESI contains text that has been redacted under assertion of privilege or other permissible protection from disclosure, full extracted text will be provided in the format of a single *.txt file for each file (i.e., not one *.txt file per *.tif image). Where ESI contains text that has been redacted under assertion of privilege or other protection from disclosure, the redacted *.tif image will be OCR'd and file-level OCR text will be provided in lieu of extracted text. Searchable text will be produced as file-level multi-page UTF-8 text files with the text file

named to match the beginning production number of the file. The full path of the text file must be provided in the *.dat data load file.

A.3 Word Processing Files. Word processing files, including without limitation Microsoft Word files (*.doc and *.docx), will be produced in the above format with tracked changes, comments, and hidden text showing.

A.4 Presentation Files. To the extent that presentation files, including without limitation Microsoft PowerPoint files (*.ppt and *.pptx), are produced in *.tif image format, such *.tif images will display comments, hidden slides, speakers' notes, and similar data in such files.

A.5 Spreadsheet or Worksheet Files. To the extent that spreadsheet files, including without limitation Microsoft Excel files (*.xls or *.xlsx), are produced in *.tif image format, such *.tif images will display hidden rows, columns, and worksheets, if any, in such files.

A.6 Parent-Child Relationships. Parent-child relationships (e.g., the associations between emails and their attachments) will be preserved. Email and other ESI attachments will be produced as independent files immediately following the parent email or ESI record. Parent-child relationships will be identified in the data load file pursuant to paragraph A.13 below.

A.7 English Language. To the extent any data exists in more than one language, the data will be produced in English, if available. If no English version of a file is available, the Producing Party shall not have an obligation to produce an English translation of the data.

A.8 Embedded Objects. Some Microsoft Office and .RTF files may contain embedded objects. Such objects typically are the following file types: Microsoft Excel, Word, PowerPoint, Project, Outlook, and Access; and PDF. Subject to claims of privilege and immunity, as applicable, objects with those identified file types shall be extracted as separate files and shall be produced as attachments to the file in which they were embedded.

A.9 Compressed Files. Compressed file types (i.e., .CAB, .GZ, .TAR. .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual files.

A.10 Encrypted Files. The Producing Party will take reasonable steps, prior to production, to unencrypt any discoverable electronically stored information that exists in encrypted format (e.g., because of password-protection) and that can be reasonably unencrypted. What constitutes a reasonable step shall be governed by the Federal Rules of Civil Procedure and the Parties agree to meet and confer concerning matters of encryption and to attempt to amicably resolve any dispute related thereto, and to move before the Court as necessary.

A.11 Scanned Hardcopy Documents.

a. In scanning hardcopy documents, multiple distinct documents should not be merged into a single record, and single documents should not be split into multiple records (i.e., hard copy documents should be logically or physically unitized).

b. If the Producing Party produces hard copy documents in scanned form, that Party agrees to provide OCR text for scanned images of hard copy documents. OCR should be performed on a document level and provided in document-level *.txt files named to match the production number of the first page of the document to which the OCR text corresponds. OCR text should not be delivered in the data load file or any other delimited text file. Alternatively, the text of ESI may be provided as separately fielded data within the Concordance delimited file as described herein.

c. In the case of an organized compilation of separate hardcopy documents—for example, a binder containing several separate documents behind numbered tabs—the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the family fields set out below.

A.12 Production Numbering.

a. In following the requirements of Paragraph A.1, the Producing Party shall take reasonable steps to ensure that attachments to documents or electronic files are assigned production numbers that directly follow the production numbers on the documents or files to which they were attached. If a production number or set of production numbers is skipped, the skipped number or set of numbers will be noted. In addition, wherever possible, each *.tif image will have its assigned production number electronically "burned" onto the image.

A.13 Data and Image Load Files.

a. Load Files Required. Unless otherwise agreed, each production will include a data load file in Concordance (*.dat) format (UTF-8 format if metadata has foreign characters) and an image load file in Opticon (*.opt) format.

b. Load File Formats.

i. Load file names should contain the volume name of the production media. Additional descriptive information may be provided after the volume name. For example, both ABC001.dat or ABC001_metadata.dat would be acceptable.

ii. Unless other delimiters are specified, any fielded data provided in a load file should use Concordance default delimiters. Semicolon (;) should be used as multi-entry separator.

iii. Any delimited text file containing fielded data should contain in the first line a list of the fields provided in the order in which they are organized in the file.

c. Fields to be Included in Data Load File. For all documents or electronic files produced, the following metadata fields for each document or electronic file, if available at the time of collection and processing and unless such metadata fields are protected from disclosure

by attorney-client privilege or work-product immunity or otherwise prohibited from disclosure by law or regulation, will be provided in the data load file pursuant to subparagraph (a), above, except to the extent that a document or electronic file has been produced with redactions. The term "Scanned Docs" refers to documents that are in hard copy form at the time of collection and have been scanned into *.tif images. The term "Email and E-Docs" refers to files that are in electronic form at the time of their collection, irrespective of the form (TIFF-Plus or native format) in which they are produced.

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
PRODBEG [Key Value]	ABC00000001	Yes	Yes	Beginning production number
PRODEND	ABC00000008	Yes	Yes	Ending production number
PRODBEGATT	ABC00000009	Yes	Yes	Beginning production number of parent in a family
PRODENDATT	ABC00001005	Yes	Yes	Ending production number of last page of the last attachment in a family
CUSTODIAN	Smith, John	Yes	Yes	Custodian(s) that possessed the document or electronic file—multiple custodians separated by semicolon
OTHER_CUSTODIANS	Doe, Jane; Jones, James	Yes	Yes	When global de-duplication is used, these are custodians whose file has been de-duplicated
NATIVEFILE	Natives\\ \00000001.xls	N/A	Yes	Path and file name for native file on production media
FILEDESC	Microsoft Office 2007 Document	N/A	Yes	Description of the type file for the produced record.
FOLDER	\My Documents\Document1.doc	N/A	Yes	Original source folder for the record produced.
FILENAME	Document1.doc	N/A	Yes	Name of original electronic file as collected.
DOCEXT	DOC	N/A	Yes	File extension for email or e-doc
PAGES	2	Yes	Yes	Number of pages in the produced document or electronic file (not applicable to native file productions).
AUTHOR	John Smith	N/A	Yes	Author information as derived from the properties of the document.
DATECREATED	10/09/2005 10:33 am	N/A	Yes	Date & time that non-email file was created as extracted from file system metadata
DATELASTMOD	10/09/2005 10:33 am	N/A	Yes	Date & time that non-email file was modified as extracted from file system metadata
SUBJECT	Changes to Access Database	N/A	Yes	"Subject" field extracted from email message or metadata properties of the document

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
FROM	John Beech	N/A	Yes	"From" field extracted from email message
TO	Janice Birch	N/A	Yes	"To" field extracted from email message
CC	Frank Maple	N/A	Yes	"Cc" or "carbon copy" field extracted from email message
BCC	John Oakwood	N/A	Yes	"Bcc" or "blind carbon copy" field extracted from email message
DATESENT	10/10/2005 10:33 am	N/A	Yes	Sent date & time of email message (mm/dd/yyyy format)
DATERCVD	10/10/2005 10:33 am	N/A	Yes	Received date & time of email message (mm/dd/yyyyformat)
CONFIDENTIALITY	HIGHLY CONFIDENTIAL	Yes	Yes	Text of confidentiality designation, if any
TEXTPATH	Text\\\.txt	Yes	Yes	Path to *.txt file containing extracted or OCR text
PRODVOL	VOL001	Yes	Yes	Name of the Production Volume

A.14 Files Produced in Native Format.

a. For any electronic file produced initially as a native file in accordance with Paragraph B.2 of the Protocol above, the file shall be given a file name consisting of a unique Bates number and, as applicable, a suitable confidentiality designation; for example, "ABC00000002_Confidential." For each such native file, the production will include a *.tif image slipsheet (i) indicating the production number of the native file, (ii) with respect to any confidential document, setting forth the full confidentiality language applicable to the native file as set out in the protective order, and (iii) stating "File Provided Natively." To the extent that it is available, the original or redacted file text shall be provided in a file-level multi-page UTF-8 text file with a text path provided in the *.dat file; otherwise the text contained on the slipsheet shall be provided in the *.txt file with the text path provided in the *.dat file.

b. For any electronic file produced in native file format following production of a TIFF-image in accordance with Paragraph B.1, the file shall be given a file name consisting of (i) the Bates number of the first page of the associated TIFF-image and (ii) as applicable, a suitable confidentiality designation. For each such native file, the production will include a new .DAT file

(i) indicating the production number of the native file, (ii) identification of the path to the native file, and (iii) linking the metadata associated with the originally produced TIFF image to the newly produced native file."

A.15 Production Media. Unless otherwise agreed, documents and ESI will be produced on optical media (CD/DVD), external hard drive, secure FTP site, or similar electronic format. Such media should have an alphanumeric volume name; if a hard drive contains multiple volumes, each volume should be contained in an appropriately named folder at the root of the drive. Volumes should be numbered consecutively (ABC001, ABC002, etc.). Deliverable media should be labeled with the name of this action, the identity of the producing Party, and the following information: Volume name, production range(s), and date of delivery.

A.16 Encryption of Production Media. To maximize the security of information in transit, any media on which documents or electronic files are produced may be encrypted by the producing Party. In such cases, the producing Party shall transmit the encryption key or password to the requesting Party, under separate cover, contemporaneously with sending the encrypted media. The receiving Parties in this matter are on notice that certain data produced may originate from custodians in the European Union and the receiving Parties therefore agree to follow the appropriate security standards in guarding access to said data.

EXHIBIT 4

From: Douglas, Jeannine
Sent: Thursday, June 29, 2023 5:48 PM
To: jshaw@shawkeller.com; arussell@shawkeller.com; nhoeschen@shawkeller.com; glocascio@kirkland.com; Bova, Justin; Dirks, Steven; kat.li@kirkland.com; austin.teng@kirkland.com; jheffernan@kirkland.com; ryan.melde@kirkland.com; ryan.kane@kirkland.com; laura.zhu@kirkland.com; vicki.merideth@kirkland.com; socrates.boutsikaris@kirkland.com; nathaniel.delucia@kirkland.com; noah.frank@kirkland.com; brian.verbus@kirkland.com; jake.rambeau@kirkland.com; SKIvantis@shawkeller.com; #Alcon-SightSciences
Cc: Sharp, Melanie; Hallowell, Taylor E.; Higgins, James; Villoslada, Caroline; mgassaway@ycst.com; Rhyu, Michelle; Armon, Orion; Strosnick, Lauren; Murdter, David; Wood, Alissa; Vanderwall, Cameron C.; Gibbs, Tracy; z/Sight Sciences Ivantis
Subject: Sight Sciences v. Ivantis, No. 21-1317-GBW-SRF - Plaintiff's Document Production
Attachments: 2023-06-29 Douglas ltr to Counsel re production .pdf

Counsel,
Please see the attached correspondence.
On behalf of Plaintiff, in the above referenced matter, please see the link below to download the following document production.
PROD26 contains Bates numbered documents SGHT0168057-SGHT0168087.
https://liquidfiles.cooley.com/link/9JFA7i7AE0bxjLONncAJKl

The password for the zip file will be sent in a separate email.
Please let me know if you should have any issues accessing the document.
Sincerely,

Jeannine Douglas
Paralegal Specialist
Cooley LLP
3175 Hanover Street ♦ Palo Alto, CA 94304-1130
Direct: 650-843-5495 ♦ Fax: 650-849-7400
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June 29, 2023

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Re: ***Sight Sciences, Inc. v. Ivantis, Inc.*****, C.A. No. 21-1317-GBW-SRF**

Dear Counsel:

Enclosed please find documents being produced by Plaintiff Sight Sciences, Inc. bearing Bates numbers SGHT0168057-SGHT0168087.

Should you have any issues accessing the document, please let me know.

Sincerely,

Cooley LLP

Jeannine A.R. Douglas
Paralegal Specialist
Enclosures

cc: Lauren Strosnick

288129141 v1

EXHIBIT 5

From: Li, Kat <kat.li@kirkland.com>
Sent: Monday, June 6, 2022 6:54 PM
To: Armon, Orion; *msharp@ycst.com; Rhyu, Michelle; Kannappan, Deepa; Murdter, David; Ross, Emily Mae-Yen
Cc: LoCascio, Gregg F.; Kane, Ryan; Bova, Justin; John Shaw; Andrew Russell
Subject: Sight Sciences v. Ivantis - ESI and Protective Orders
Attachments: Sight Sciences-Ivantis ESI Redline.pdf; Draft ESI Order - KE.docx; Sight Sciences-Ivantis PO Redline.pdf; Draft Sight Sciences Protective Order - KE.docx

[External]

Counsel—Attached please find our edits to the proposed ESI and protective orders in both clean Word and redline PDF versions.

Please let us know if you would like to discuss.

Best,
Kat

Kat Li

KIRKLAND & ELLIS LLP
401 Congress Avenue, Austin, TX 78701
T +1 512 678 9167 **F** +1 512 678 9101

kat.li@kirkland.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiffs, IVANTIS, INC., Defendant.	C.A. No. 1:21-cv-01317-~~VAC~~VAC-SRF JURY TRIAL DEMANDED

STIPULATION AND [PROPOSED] ORDER RE:
DISCOVERY OF ELECTRONICALLY STORED INFORMATION

Plaintiff Sight Sciences, Inc. and Defendant Ivantis, Inc. stipulate to and respectfully ask the Court to enter the following ORDER regarding discovery of Electronically Stored Information ("ESI"):

1. **Purpose**. This Order replaces the ESI portion of the District of Delaware's Default Standard for Discovery and supplements the Federal Rules of Civil Procedure and any other applicable orders and rules.

2. **Cooperation**. The Parties are aware of the importance the Court places on cooperation and commit to continue to consult and cooperate reasonably as discovery proceeds. The failure of counsel or the Parties to litigation to cooperate in facilitating and reasonably limiting discovery requests and responses raises litigation costs and contributes to the risk of sanctions. An attorney's zealous representation of a client is not compromised by conducting discovery in a cooperative manner.

3. ~~2.~~ **Definitions**

The following definitions apply to this Order:

a. **"Database"** means an electronic collection of structured data (often maintained in a non-custodial manner).

b. **"Family"** means a group of documents that are maintained as a single unit in the ordinary course of business (*e.g.*, an email and its attachments).

c. **"ESI"** or **"Electronic Document"** means electronically stored information as defined in FRCP 34(a)(1)(A).

d. **"Extracted Text"** refers to the result of the process by which content of an Electronic Document is electronically extracted during e-discovery processing.

e. **"Native Format"** means the default format of ESI created by its associated software program and also includes the export format of documents that are not maintained in a usable Native Format.

f. **"Optical Character Recognition"** or **"OCR"** refers to the result of the process by which a hard copy or non-searchable Electronic Document is scanned by a computer to capture text from the face of the document.

g. **"Privileged Information**" refers to information subject to a claim of attorney-client privilege, work-product protection, or other privilege or immunity.

h. **"Producing Party"** means any Party to this proceeding who produces documents or information under this Order.

i. **"Receiving Party"** means any Party to this proceeding who receives documents or information under this Order.

4. ~~3.~~ **Production format and metadata**.

a. **Format**. Subject to the exceptions for documents to be produced in Native Format, documents will be produced as Bates-stamped tagged image file format ("~~Tiff~~TIFF") images

accompanied by an image load file, a data load file with fielded metadata, document-level ~~e~~Extracted ~~t~~Text for ESI, and OCR text for scanned hard copy documents and ESI that does not contain extractable text. The Bates stamp shall appear in the lower right-hand corner of all images and shall be a unique, consistently formatted identifier that will: (1) be consistent across the production; (2) contain no special characters; and (3) be numerically sequential within a given file.

b. ~~Tiff~~**TIFF images**. ~~Tiff~~TIFF images will be produced in black and white, 300~~x300 dpi~~DPI Group IV single-page format and will be consecutively Bates-stamped.

(i) Images will include the following content where present:

a. For word processing files (*e.g.*, Microsoft Word): Comments, "tracked changes," similar in-line editing and all hidden content.

b. For presentation files (*e.g.*, Microsoft PowerPoint): Speaker notes, comments, and all other hidden content.

~~c. For spreadsheet files (*e.g.*, Microsoft Excel – if applicable): Hidden columns, rows, and sheets; comments, and any similar in-line editing or hidden content.~~

(ii) In the event that black-and-white imaging renders a document difficult to read (*e.g.*, Word documents with tracked changes from multiple authors), the Receiving Party may request that the Producing Party re-produce the document in color JPEG, 300 DPI Group IV single-page format. The Requesting Party must identify the pages by Bates number that it wishes to receive as color images, limited to a reasonable number of pages.

c. **Native files**. Spreadsheet files (*e.g.*, Microsoft Excel and .csv files) and Media files (*e.g.*, .mp3, .wmv, etc.) shall be provided in Native Format with a single placeholder image bearing the Bates number and confidentiality designation.

A party may request reproduction in native format of a reasonable number of files identified by Bates number if the default production format renders them difficult to review, creates formatting errors, or degrades legibility (*e.g.*, PowerPoint presentations).

The parties will meet-and-confer to discuss a suitable production format for any proprietary or non-standard file types that require special software or technical knowledge for review, Databases and Database reports, and any document types that cannot be accurately rendered or reviewed in image format.

d. **Deduplication.** ~~The parties will use industry standard~~"Duplicate ESI" means files that are exact duplicates based on the files' MD5 or SHA-1 hash values ~~at the Family level to globally~~. The Producing Party need produce only a single copy of responsive ~~ded~~Duplicate ~~all files identified for production~~ESI. Stand-alone Electronic Documents will not be compared to email attachments for deduplication purposes. Hard copy documents containing handwritten notes will not be considered as duplicative of any other document.

e. **Document Unitization.** Where documents with attachments are produced, they will be attached in the same manner as included in the original file. Unless documents contain solely Privileged Information, parties will produce complete Document Families where any portion of the Family contains relevant information. Where documents are produced and the full Family is not included, the Producing Party will identify the missing attachments by means of a "place holder" file explaining why the document was not produced. For example, if a document is withheld on privilege grounds, the place holder would state "Withheld for Privilege."

Where the Producing Party converts paper documents into electronic format, distinct documents must not be merged into a single record, and single documents must not be split into multiple records.

Documents that are segregated or separated from other documents, whether by inclusion of binders, files, dividers, tabs, clips or any other method, will be produced in a manner that reflects these divisions.

f. **Metadata fields**. Aside from metadata fields generated during eDiscovery processing and production (*e.g.*, Bates numbers, hash and custodian values, etc.), the Producing Party is not obligated to produce metadata from a document if metadata is not reasonably available. The parties agree to produce the following metadata fields where applicable: PROD_VOL, Custodian, All Custodians, Email Subject, ~~Conversation Index,~~ From, To, CC, BCC, Date Sent, Time Sent, ~~Date Received, Time Received,~~ Filename, Author, Date Created, Date Last Modified, MD5 Hash, File ~~Size, File~~ Extension, ~~Control~~Bates Number Begin, ~~Control~~Bates Number End, ProdBeg Attachment ~~Range,~~, ProdEnd Attachment ~~Begin~~, and ~~Attachment End~~Confidentiality (or the equivalent thereof). Descriptions of each metadata field are listed below.

Field	**Description**
PROD_VOL	Name of the Production Volume.
Custodian	Custodian who possessed the document or electronic file.
All Custodians	When global deduplication is used, these are custodians whose file has been deduplicated; multiple custodians separated by semicolon (*e.g.* "Doe, Jane; Jones, James; Smith, Bob.")
Email Subject	"Subject" field extracted from email message.
From	"From" field extracted from email message.
To	"To" field extracted from email message.
CC	"CC" or "carbon copy" field extracted from email message.
BCC	"BCC" or "blind carbon copy" field extracted from email message.
Date Sent	Sent date of email message (mm/dd/yyyy format).
Time Sent	Sent time of email message, time zone set to GMT.
Filename	Original file name.

Author	If available, the person(s) who created, wrote, reviewed, signed, or approved the document. If no author is present, a default value of "None" will be coded.
Date Created	Date the document was created.
Date Last Modified	Date the document was last modified.
MD5 Hash	MD5 Hash value for ESI.
File Extension	File extension describing the type of document.
Bates Number Begin	The production ID number for the first page of the document.
Bates Number End	The production ID number for the last page of the document.
ProdBeg Attachment	The production ID number for the first page of the parent document.
ProdEnd Attachment	The production ID number for the last page of the last attachment to the parent document.
Confidentiality	Text of confidentiality designation, if any.

5. ~~4.~~ **Production Deliverable.**

a. **Load Files.** A Concordance compatible data load file will be provided with each production volume containing a header row listing all metadata fields included in the volume. Image load files will be produced in ~~Concordance/~~Opticon compatible format. Load file names should contain the volume name of the production media. Additional descriptive information may be provided after the volume name. For example, both ABC001.dat or ABC001_metadata.dat would be acceptable. Unless other delimiters are specified, any fielded data provided in a load file should use Concordance default delimiters. Semicolon (;) should be used as multi-entry separator. Any delimited text file containing fielded data should contain in the first line a list of the fields provided in the order in which they are organized in the file.

b. **Delivery**. Productions shall be delivered via secure online data transfer (*e.g.*, secure FTP site), or on an external hard drive if the size of a production makes online transfer impractical.

c. **Encryption.** To maximize the security of information in transit, the Parties shall encrypt any media on which documents are produced. In such cases, the Producing Party will

transmit the encryption key or password and applicable instructions to the Receiving Party, upon receipt of the encrypted media.

d. **Extracted Text/OCR.**

(i) Electronically Extracted Text must be provided if available for documents collected from electronic sources. Text generated via OCR shall be provided for all documents that do not contain electronically extractable text (*e.g.*, non-searchable PDF files or JPG images), for documents redacted in image format, and hard copy documents. The parties will not degrade the searchability of documents as part of the document production process.

(ii) Document text will be produced as separate, document-level text files and will not be embedded in the metadata load file.

(iii) Text files will be named according to the beginning Bates number of the document to which they correspond.

(iv) If a document is provided in Native Format, the text file will contain the Extracted Text of the native file.

6. ~~5.~~ **Document preservation**.

a. All parties are obligated to take reasonable and proportionate steps to preserve relevant information in the party's possession, custody, or control. The parties agree to meet and confer if they identify discoverable ESI sources that are not covered by the technical specifications in this Order and agree to modify as needed.

b. To reduce the costs and burdens of preservation and to ensure proper ESI is preserved, the parties agree that unless otherwise ordered by the Court upon a motion of a party,

the information sources listed in Schedule A need not be preserved, searched, reviewed, or produced.

7. ~~6.~~ **Privilege**.

a. Pursuant to Section 1~~2~~1 of the Stipulated Protective Order and Rule 502(d) of the Federal Rules of Evidence, the production or disclosure of any privileged or otherwise protected documents (as defined by Fed. R. Civ. P. 34(a)(l)) and accompanying metadata (collectively, "Documents"), shall not result in the waiver of any privilege or other protection (including, without limitation, the attorney-client privilege, the work-product doctrine, the joint defense privilege, or other applicable privilege) associated with such Documents in this case or in any other federal or state proceeding. The Parties will not conduct an inquiry under FRE 502(b) to determine whether information was produced inadvertently. Instead, the Parties will determine inadvertence solely based on the good faith representation of the Producing Party.

b. Fed. R. Civ. P. 26(b)(5)(B) governs the proper procedure for the notification and return of Privileged Information when identified by the Producing Party.

c. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work-product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI.

d. Activities undertaken in compliance with the duty to preserve information are protected from disclosure and discovery under Fed. R. Civ. P. 26(b)(3)(A) and (B).

e. The parties agree to furnish logs that comply with Fed. R. Civ. P. 26(b)(5) and any other legal requirements for all documents withheld or redacted on the basis of privilege,

attorney work product, or similar doctrines, in accordance with Section 132.4 of the Stipulated Protective Order.

8. **Email Production Requests**

a. Consistent with the proportionality standard set forth in Rule 26(b)(1), the Parties agree to cooperate in identifying appropriate limits on discovery, including phased discovery and limits on the number of custodians, on discoverable data sources, on the relevant period, and on the permissible scope of requests for production, specifically including the permissible scope of requests for emails. Requests for production of ESI, including requests for emails as described below, shall be reasonably targeted, clear, and as specific as possible, rather than general discovery of a product or business. Absent good cause, the Parties shall not be obligated to collect or produce ESI created after the date of filing of the Complaint in this action (D.I. 1). General ESI production requests under Rules 34 and 45 of the Federal Rules of Civil Procedure, or compliance with a mandatory disclosure order of this Court, shall not include email or other forms of electronic correspondence (collectively, "email"). To obtain email, parties must propound specific production requests.

(i) Email production shall be phased to occur timely after the parties have exchanged (1) initial disclosures, (2) a specific listing of likely email custodians, (3) a specific identification of the five (5) most significant listed email custodians in view of the pleaded claims and defenses, (4) infringement contentions and accompanying documents pursuant to the Scheduling Order entered in This Action, (5) invalidity contentions and accompanying documents pursuant to the Scheduling Order in this Action, and (6) preliminary information relevant to damages. The exchange of this information shall occur at the time required under

the Federal Rules of Civil Procedure, Local Rules, the Scheduling Order in this Action, or by order of the Court. Each requesting party may also propound up to three written discovery requests per producing party to identify the proper email custodians, proper search terms, and proper time frame for email production requests. The Court may allow additional discovery upon a showing of good cause.

(ii) Email production requests shall identify the custodian, search terms, and time frame. As described below, the parties shall cooperate to identify the proper custodians, proper search terms, and proper time frame. Each Requesting Party shall limit its email production requests to a total of five (5) custodians per producing party for all such requests. The parties may jointly agree to modify this limit without the Court's leave. The Court shall consider contested requests for additional or fewer custodians per producing party, upon a showing of a distinct need based on the size, complexity, and issues of this specific case.

(iii) Each Requesting Party shall limit its email production requests to a total of seven (7) search terms per custodian per party to be applied to email. The parties may jointly agree to modify these limits without the Court's leave. Subject to paragraph 8.a(vi), the Court shall consider contested requests for additional or fewer search terms per custodian, upon a showing of a distinct need based on the size, complexity, and issues of this specific case. The search terms shall be narrowly tailored to particular issues.

(iv) An email production request that results in more than 500 hits inclusive of family members for a given search term for a single custodian shall be presumed

unreasonable. Absent party agreement, the party propounding that email production request will have the burden to prove to the Court that the request is proper. A "hit" is defined as a document matching a search term plus all of that document's family members (*e.g.*, an email plus its attachments); for example, if a search term matches one email that has two attachments, that counts as three hits regardless of whether the attachments also contain the search term.

(v) Indiscriminate terms, such as the producing company's name (*e.g.*, "Ivantis") or its product name (*e.g.*, "Hydrus"), are inappropriate unless combined with narrowing search criteria that sufficiently reduce the risk of overproduction. A conjunctive combination of multiple words or phrases (*e.g.*, "implant" and "stent") narrows the search and shall count as a single search term. A disjunctive combination of multiple words or phrases (*e.g.*, "implant" or "stent") broadens the search, and thus each word or phrase shall count as a separate search term unless the words or phrases are variants of the same word or phrase. Use of narrowing search criteria (*e.g.*, "and," "but not," "w/x") is encouraged to limit the production and shall be considered when determining whether to shift costs for disproportionate discovery.

(vi) It is expected that the parties will meet and confer and iterate on search terms to arrive at a set of email production requests that generate no more than 500 hits per search term, per custodian (*i.e.*, a maximum total number of documents of 17,500 per side). During each iteration, the party to whom an email production request is directed must provide hit counts for each search term and accept or object on a search term-by-search term basis. Disclosure of these hit counts will not result in

waiver of any privileged subject matter. The parties agree that, if a given search term returns more than 500 hits, that does not necessarily indicate that all of the hit- upon documents are relevant. The parties will not argue that a hit count of more than 500 hits for a proposed search term "proves" the appropriateness of the search term.

(vii) The parties agree that, for email production requests, the final search results from the final search terms (*i.e.*, the results produced by a search that meets the criteria described in paragraphs 8.a(iii)-8.a(vi) above) will be reviewed for privilege. Otherwise, the final email search results will be presumptively responsive.

9. **Non-Custodial Databases.** If discoverable data from any Database can be produced in the form of an already existing and reasonably available report, the Producing Party may collect and produce the data in that report in accordance with Sections 4 and 5 above. If an existing report form is not reasonably available, the Producing Party may make reasonable efforts to export from the Database discoverable information in the form of a new report or in a format compatible with Microsoft Excel or Microsoft Access and may produce such information in that native format.

10. ~~7.~~ **Reproduction of third-party ESI**. Notwithstanding anything to the contrary herein, any party that produces documents produced to it by a third party, such as in response to a subpoena, may produce such documents in the format in which they were produced by the third party.

11. ~~8.~~ **Modification**. Unless specifically stated otherwise, the parties may jointly agree to modify this Stipulation without the Court's leave. Any such modification shall be in a writing signed by the parties or their respective counsel. If the parties cannot resolve their disagreements regarding a proposed modification, the parties reserve the right to seek relief ~~from~~through the Court's discovery dispute procedures.

12. ~~9.~~ **Cost shifting**.

a. As in all cases, costs may be shifted for disproportionate ESI production requests pursuant to Federal Rule of Civil Procedure 26. Likewise, a party's nonresponsive or dilatory discovery tactics are cost-shifting considerations.

b. A party's meaningful compliance with this Order and efforts to promote efficiency and reduce costs will be considered in cost-shifting determinations, but nothing in this order shall affect a producing party's right to seek reimbursement for costs associated with collection, review, and/or production of ESI.

13. ~~10.~~ **Federal or local rules**. Except as expressly stated, nothing in this Order affects the parties' discovery obligations under the Federal or Local Rules.

SCHEDULE A

1. Deleted, slack, fragmented, or other data only accessible by forensics.

2. Random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system.

3. On-line access data such as temporary internet files, history, cache, cookies, and the like.

4. Data in metadata fields that are frequently updated automatically, such as last- opened dates.

5. Back-up data that are substantially duplicative of data that are more accessible elsewhere.

6. Voice messages.

7. Instant messages that are not ordinarily printed or maintained in a server dedicated to instant messaging.

8. Electronic mail or pin-to-pin messages sent to or from mobile devices (e.g., iPhone and Blackberry devices), provided that a copy of such mail is routinely saved elsewhere.

9. Other electronic data stored on a mobile device, such as calendar or contact data or notes, provided that a copy of such information is routinely saved elsewhere.

10. Logs of calls made from mobile devices.

11. Server, system or network logs.

12. Electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report.

13. Data remaining from systems no longer in use that is unintelligible on the systems in use.

Dated: June 6, 2022

Respectfully submitted,

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IT IS SO ORDERED, this _____ day of _____ 20__.

United States ~~District~~Magistrate Judge

Summary report: **Litera Compare for Word 11.0.0.61 Document comparison done on 6/6/2022 12:21:42 PM**	
Style name: Color (Kirkland Default)	
Intelligent Table Comparison: Active	
Original filename: Cooley Draft ESI Order.docx	
Modified DMS: iw://dms.kirkland.com/LEGAL/86340285/16	
Changes:	
Add	80
~~Delete~~	36
~~Move From~~	0
Move To	0
Table Insert	1
~~Table Delete~~	0
Table moves to	0
~~Table moves from~~	0
Embedded Graphics (Visio, ChemDraw, Images etc.)	0
Embedded Excel	0
Format changes	0
Total Changes:	117

EXHIBIT 6

[redacted]

From: "Shervin Korangy" <skorangy@gmail.com>
Sent: Sat, 27 Aug 2011 06:17:17 +0000 (UTC)
To: "David Badawi" <davidbadawi@gmail.com>; "Selnick, Jesse" <Selnick@blackstone.com>; paul@sightsciences.com
Subject: Re: [FWD: Your questions]

David - thanks for the reply. Its been motivating to Jesse and I to make sure the Badawi brothers create ophthalmic history here!!

Also, I hope you are a frequent user of our Alcon products. They are the best in the industry and we continue to strive to meet patient and physician needs through our innovation!!

Single malt and a couple cigars in 3 yrs after we get our European clinical data!!

On 8/27/11, David Badawi <davidbadawi@gmail.com> wrote:
> Hi Jesse,
> You know how it is--just wheelin, dealin, and healin. Seriously though, many
> thanks to you and Shervin for the huge and successful effort!
>
> I hope you are doing well--maybe we will all be in the same place one of
> these days to celebrate. I owe you and Shervin and Paul a good glass of
> single malt scotch.
>
> David
>
> On Fri, Aug 26, 2011 at 6:10 PM, Selnick, Jesse
> <Selnick@blackstone.com>wrote:
>
>> Sorry I just got excited to see an email with your brother on it. What's
>> up david?
>>
>>
>> ----------
>> *From*: paul@sightsciences.com <paul@sightsciences.com>
>> *To*: Shervin Korangy <skorangy@gmail.com>; Selnick, Jesse
>> *Sent*: Fri Aug 26 19:09:03 2011
>> *Subject*: [FWD: Your questions]
>>
>> sherv, please feel free to select whatever you want from the comments
>> below
>> and attachments. honestly, if someone doesnt think good canaloplasty
>> clinical data is good, then it's hard to have a productive discussion.
>> it's
>> like when Ben Sharp was about to destroy someone in a biochemistry class
>> at
>> U of C, he premised his slaughter by saying "I need to assume that you are
>> logical...."
>>
>> -------- Original Message --------
>> Subject: Your questions
>> From: David Badawi <davidbadawi@gmail.com>
>> Date: Fri, August 26, 2011 2:14 pm
>> To: paul@sightsciences.com
>>
>> Hi Paul,
>> I received the feedback and questions from the glaucoma
>> specialist/investor

>> that you mentioned. Great questions! The specialist pointed out that
>> canaloplasty does not routinely lower intraocular pressure to satisfactory
>> levels when compared to trabeculectomy. I have attached several
>> references-peer reviewed articles-to the contrary. Two points worth
>> considering:
>> 1. Canaloplasty does consistently lower pressure to satisfactory levels
>> (almost as close to trab but without the massive complications), but is
>> technically difficult to perform and gradual loss of suture tension may
>> limit its long-term efficacy-two shortcomings that we do NOT suffer from
>> with our approach.
>>
>> 2. Without oversimplifying this, anyone who does trabeculectomies knows it
>> is not a benign surgery-FULL of complications, and there is a real need
>> for
>> a safe alternative. That's why so few of the surgeries are done and so
>> many
>> patients are on more costly lifelong medications.
>>
>> In terms of most of the resistance to outflow being downstream from
>> Schlemm's canal, I suspect that there is a typo or misunderstanding there.
>> Research tells us that most resistance to outflow is at the
>> juxtacanlaicular
>> trabecular meshwork which would be PROXIMAL to Schlemm's rather than
>> distal.
>> Our Helix certainly addresses this issue by maximally restoring meshwork
>> surface area and its inherent porosity and lifting it up and away from the
>> outer walls of the canal.
>>
>> 'Trabeculectomy' surgery, which I presume the glaucoma specialist believes
>> in, means to 'cut the trabeculum.' This is proximal to Schlemm's canal,
>> not
>> distal. Trabeculectomies work by cutting the proximal trabecular meshwork
>> and bypassing an often collapsed Schlemm's to allow fluid to drain in the
>> DISTAL low pressure conjunctival venous system (which likely follows
>> central
>> venous pressure--around 6-8mm Hg--a real good and low pressure).
>>
>> Like trabeculectomy, we target the source of the problem--the trabecular
>> meshwork and a collapsed Schlemm, but we lack the adverse reactions of
>> trabeculectomy making us a more attractive surgical option and a real
>> competitor to medications as well.
>>
>> Anyway, hope whtis helps. Happy to elaborate as needed.
>>
>> David
>>
>>
>>
>>
>>
>> ----------
>> Please open the following attachment for important Blackstone disclaimer
>> information regarding this e-mail communication.
>>
>
>
>
> --
> David Badawi, M.D.
> Ophthalmologist,
> Northwest Eye Physicians
> 1588 North Arlington Heights Rd.
> Arlington Heights, Illinois 60004
>
> Phone: 847-392-9220

> Fax: 847-392-9252
>

EXHIBIT 7

Comparison of Surgical Outcomes Between Canaloplasty and Trabeculectomy at 12 Months' Follow-Up

Ramesh S. Ayyala, MD, FRCS,[1] *Amina L. Chaudhry, MD,*[1] *Carola B. Okogbaa, MD,*[1] *David Zurakowski, PhD*[2]

Purpose: To compare operative outcomes of patients after canaloplasty and trabeculectomy through 12 months' follow-up.

Design: Retrospective, nonrandomized, comparative case series.

Participants: We included 33 eyes of 33 patients who underwent canaloplasty and 46 eyes of 46 patients who underwent trabeculectomy with 12 months' of postoperative follow-up.

Methods: Patients with open-angle glaucoma who underwent either canaloplasty or trabeculectomy with mitomycin C to control the intraocular pressure (IOP) between January 2007 and December 2008 were included. All surgeries were performed by a single surgeon (R.S.A.).

Main Outcome Measures: Change in IOP, visual acuity (VA), postoperative medications, failure based on IOP (>18 or <4 mmHg at 1 year) or second operative procedure (any eye requiring reoperation) and complication rates at 12 months.

Results: There were no differences in demographics, previous surgery, or preoperative and postoperative VA between the groups. The mean percentage reduction in IOP from preoperative values at 12 months after surgery was 32% (±22%) for the canaloplasty group compared with 43% (±28%) for the trabeculectomy group ($P = 0.072$, Student *t* test). The median reduction in the number of medications at 12 months' follow-up was 3 in the trabeculectomy group and 2 in the canaloplasty group ($P = 0.064$). A higher percentage of patients treated with canaloplasty than trabeculectomy (36% vs. 20%) required postoperative medications, although this did not attain significance ($P = 0.12$). Failure based on IOP (IOP >18 or <4 mmHg at 12 months) was 12.1% (4/33 patients) for the canaloplasty group and 4.3% (2/46 patients) for the trabeculectomy group ($P = 0.23$, Fisher exact test). There was no difference in surgical failure rates between the canaloplasty (n = 5; 15%) and trabeculectomy (n = 5; 11%) groups ($P = 0.74$).

Conclusions: Canaloplasty and trabeculectomy both achieved significant reduction in IOP at 12 months.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references.
Ophthalmology 2011;xx:xxx

Operative management of patients with open-angle glaucoma includes trabeculectomy and nonpenetrating surgeries such as canaloplasty. Canaloplasty is a new operative procedure that involves viscodilation of the Schlemm canal with the placement of an intracanalicular tension suture.[1,2] Several studies[1–4] have analyzed the surgical success of each of these procedures, but no study to date has compared the surgical success of canaloplasty against the gold standard trabeculectomy with mitomycin C (MMC) in the management of patients with open-angle glaucoma. The present study compares the surgical outcomes among the 2 procedures: Trabeculectomy with MMC and canaloplasty without MMC.

Materials and Methods

This retrospective, nonrandomized, comparative study received institutional review board approval. All surgeries were performed by a single surgeon (RSA). Medical records of consecutive patients who underwent either trabeculectomy with MMC or canaloplasty in an eye with advanced open-angle glaucoma treated in the Glaucoma Service at the Tulane University Health Sciences Center from January 2007 to December 2008 were reviewed. The decision to perform canaloplasty or trabeculectomy was based on the prior approval of canaloplasty by the insurance companies. Because canaloplasty is a new operative procedure, we had difficulty obtaining prior authorization with certain insurance companies. All patients whose insurance companies preauthorized the canaloplasty procedure underwent canaloplasty. The rest of the patients underwent trabeculectomy with MMC. A total of 102 canaloplasty procedures in 87 patients and 156 trabeculectomy surgeries in 112 patients were performed during the study period. Only 1 eye of each patient with minimum 12 months' follow-up after the glaucoma procedure was included in the study. In those patients who had surgery in both eyes, only 1 eye was used for the study purposes, chosen randomly using a computerized program. Similarly, in those patients who had trabeculectomy in 1 eye and canaloplasty in the other eye, only 1 procedure/eye (either trabeculectomy or canaloplasty) was chosen randomly.

We documented for each patient age, race, gender, type of glaucoma, past or concurrent surgeries, preoperative and postoperative visual acuity (VA), intraocular pressure (IOP), number of

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glaucoma medications, and postoperative complications including the incidence of choroidal effusions, suprachoroidal hemorrhage, and the status of the bleb. Postoperative information was gathered at 1 day, 1 week, and 1, 3, 6, 9, and 12 months.

Operative Techniques

The canaloplasty procedure was performed in the standard fashion previously described.[1,2] Briefly, after conjunctival dissection at the 12 o'clock limbus, a 5×5-mm partial thickness (50%) scleral flap was dissected followed by a 4×4-mm inner scleral flap at 95% depth. The inner flap dissection was carried forward until the Schlemm canal was unroofed. The dissection was then carried into clear cornea to create a 0.3-mm Descemet's window and then the inner scleral flap was removed. This was followed by viscodilation of the canal using sodium hyaluronate 1.4% (Healon GV, Advanced Medical Optics, Inc., Santa Ana, CA) with the help of an ophthalmic microcatheter (iTrack-250A, iScience Interventional, Inc., Menlo Park, CA). Inward traction was applied to the dilated Schlemm's canal by inserting a 10-0 Prolene suture (Ethicon, Inc., Somerville, NJ) with the help of the microcatheter, which was then tightly tied in a loop with a slip knot. The scleral flap was secured back to the sclera with four 10-0 nylon sutures to create a watertight closure. The conjunctiva was then secured to the limbus with 10-0 Vicryl sutures (Ethicon, Inc.).

Trabeculectomy was performed using previously published standardized technique.[3] Briefly, after conjunctival dissection, a partial thickness corneoscleral flap (50% depth) was dissected. This was followed by the application of MMC (0.4 mg/ml) using Weck-cel sponge pieces soaked in MMC under the scleral flap and conjunctiva for approximately 45 seconds (range, 30–60). A punch was used to perform a keratectomy/sclerectomy followed by peripheral iridectomy. The scleral flap was secured to the sclera with 2 interrupted 10-0 nylon sutures. A 10-0 Vicryl suture was used to secure the conjunctiva to the limbus. A fornix-based conjunctival flap was used in all cases.

Statistical Analysis

The IOP data were summarized by mean values and standard deviations and VA was expressed in terms of the mean and standard error in logarithm of the minimum angle of resolution units. Gender, race, eye (left, right), and previous surgery were compared between groups using the Fisher exact test; the Student *t* test was used to assess age differences. Baseline IOP, VA, and number of medications were compared between canaloplasty and trabeculectomy groups as well as between race and gender. At 12 months, IOP failure was assessed using >18 mmHg as the criterion and rates compared between the 2 groups using the Fisher exact test. Repeated-measures analysis of variance with Bonferroni adjustment was used to compare canaloplasty and trabeculectomy groups with respect to IOP and VA from preoperative baseline to 12 months.[5] The median number of medications (preoperatively and at 6 and 12 months) were compared between groups using the nonparametric Mann–Whitney *U* test with changes in number of medications at 6 and 12 months relative to baseline within each group analyzed by the Wilcoxon signed-ranks test.[6] The Fisher exact test was used to compare failure rates, specific complications, and the proportion of patients requiring postoperative medications at 12 months between the groups. Statistical analysis was performed using the SPSS software package (version 18.0, SPSS Inc./IBM, Chicago, IL). Two-tailed $P < 0.05$ was considered significant. Power analysis indicated that a minimum sample size of 18 eyes in each group would provide 80% power to detect significant mean postoperative differences of 4 mmHg in IOP between the 2 groups assuming a standard deviation of 4 mmHg (effect size = 1.0) using analysis of variance version 7.0 (nQuery Advisor, Statistical Solutions, Saugus, MA).

Failure was defined in 2 different ways: First, IOP failure was defined as eyes with an IOP >18 mmHg with or without glaucoma medications or IOP <4 mmHg at 12 months. Second, operative failure was defined as any eye requiring reoperation either after a complication or after failure of the surgery with elevated IOP, or decrease in vision by >2 lines as a result of the surgery. Bleb revision with MMC injection at the slit lamp was not considered as a failure.

Table 1. Demographic Characteristics of the Two Study Groups

Variable	Canaloplasty (n = 33)	Trabeculectomy (n = 46)	*P* Value*
Age (yrs)			0.12
Mean ± standard deviation	68.3±10.0	64.5±11.7	
Range	52–89	42–97	
Gender			0.66
Male	17 (52%)	26 (56%)	
Female	16 (48%)	20 (44%)	
Race			0.37
Caucasian	17 (52%)	19 (41%)	
African American	16 (48%)	27 (59%)	
Side			0.50
Left eye	13 (39%)	22 (48%)	
Right eye	20 (61%)	24 (52%)	
Previous surgery			0.20
Yes	14 (42%)	13 (28%)	
No	19 (58%)	33 (72%)	

*No significant differences between the 2 groups.

Results

Thirty-three eyes of 33 patients who underwent canaloplasty and 46 eyes of 46 patients who underwent trabeculectomy were included in the study. All 77 patients were followed for a minimum of 12 months. No differences were found with respect to age ($P = 0.12$), gender ($P = 0.66$), race ($P = 0.37$), right versus left eye ($P = 0.50$), or previous surgery before the glaucoma procedure ($P = 0.20$) between the 2 study groups (Table 1).

Numbers of glaucoma medications at baseline and follow-up were comparable between the 2 study groups (Table 2). A higher percentage of patients treated with canaloplasty than trabeculectomy (36% vs. 20%) required postoperative medications, although this did not attain significance ($P = 0.12$, Fisher exact test). Both groups showed reductions in median number of medications between preoperative versus 6 and 12 months' follow-up that were significant ($P < 0.001$, Wilcoxon signed-ranks test). With respect to changes in glaucoma medications between preoperative baseline and 12 months, the median reduction was 2 medications (interquartile range, 1–3; range, 0–3) for canaloplasty group and 3 medications (interquartile range, 2–3; range, 0–4) in the trabeculectomy group ($P = 0.064$, Mann–Whitney *U* test). The reduction in the number of medications at 12 months' follow-up was greater with trabeculectomy than canaloplasty (median reductions, 3 vs. 2 medications), the difference between the surgical groups was not significant ($P = 0.064$).

Comparison of the percentage of patients with IOP failure at 12 months (i.e., IOP >18 mmHg) after canaloplasty was 12.1% (4/33) and after trabeculectomy was 4.3% (2/46); this difference

Table 2. Glaucoma Medications and Surgical Failures in the Study Groups

Medications, n (%)	Canaloplasty (n = 33)	Trabeculectomy (n = 46)	P Value
Preoperative			0.35
0	1 (3%)	1 (2%)	
1	2 (6%)	0 (0%)	
2	12 (36%)	15 (33%)	
3	16 (49%)	29 (63%)	
4	2 (6%)	1 (2%)	
6 months' follow-up			0.27
0	10 (30%)	15 (33%)	
1	2 (6%)	4 (9%)	
2	6 (18%)	8 (17%)	
3	3 (9%)	7 (15%)	
4	8 (24%)	12 (26%)	
5	4 (12%)	0 (0%)	
12 months' follow-up			0.25
0	21 (64%)	37 (80%)	
1	4 (12%)	5 (11%)	
2	7 (21%)	3 (7%)	
3	1 (3%)	1 (2%)	
Any medications	12 (36%)	9 (20%)	0.12
Failure of procedure	5 (15%)	5 (11%)	0.74

Both groups had a significant reduction in number of medications at 6 and 12 months compared with preoperative ($P < 0.001$, Wilcoxon signed-rank test).

was not significant ($P = 0.23$, Fisher exact test). Multiple logistic regression analysis was used to assess whether IOP failure at 12 months (i.e., >18 mmHg) was significantly different between the 2 groups, after adjustment for 5 covariates: Age, gender, race, previous surgery, and preoperative IOP. The results indicated no group differences in IOP failure after covariate adjustment ($P = 0.24$), and no significant effects of age ($P = 0.45$), race ($P = 0.50$), gender ($P = 0.87$), previous surgery ($P = 0.89$), or preoperative IOP ($P = 0.86$) on IOP outcome at 12 months.

The mean percentage change in IOP from preoperative values to 12 months after the surgery was 32% (±22%) for canaloplasty group compared with 43% (±28%) for trabeculectomy group ($P = 0.072$, Student t test). Because one of the main purposes of the study is to compare the IOP reduction from operative intervention alone without the aid of postoperative topical glaucoma medications, we further analyzed the IOP data using 3 separate inclusion criteria (Tables 3, 4, and 5). Table 3 details the IOP of the entire group. Table 4 analyzes the data after excluding the 10 patients who were considered to be surgical failures because these patients underwent a second glaucoma-related procedure (either for failed primary surgery or to repair a postoperative complication). Table 5 illustrates the data after exclusion of those patients who either required topical glaucoma medications to control the IOP at 12 months or were considered surgical failures. All 3 tables show a significant decrease in IOP in both groups over a 12-month period.

Multivariable repeated-measures analysis of variance controlling for age ($P = 0.90$), gender ($P = 0.72$), race ($P = 0.05$), previous surgery ($P = 0.14$), and preoperative IOP ($P < 0.001$) was performed to adjust for possible confounding factors or imbalances as well as the influences of these 5 covariates on IOP. This revealed significant differences in mean IOP between the canaloplasty and trabeculectomy groups at 1 day (9.9 vs. 5.7 mmHg; $P = 0.02$), 1 week (12.5 vs. 6.4 mmHg; $P < 0.01$), 1 month (12.2 vs. 8.0 mmHg; $P<0.01$), and at 12 months (13.2 vs. 10.7 mmHg; $P = 0.02$) but no significant difference at 3 ($P = 0.14$), 6 ($P = 0.27$), or 9 months ($P = 0.08$; Table 5; Fig 1).

Table 6 demonstrates no group differences in logarithm of the minimum angle of resolution acuity (all visits; $P > 0.20$), and that the lack of group differences remained after adjusting for age, gender, race, and previous surgery by multiple regression analysis, where none of these factors influenced acuity (all visits; $P > 0.30$).

If we consider failure based on reoperation only, then in the canaloplasty group of 33 patients, there were 5 failures (15%; 3 patients with Ahmed valve and 1 with Express shunt, all in the first 3 months) and 1 patient with trabeculectomy (at 9 months). In the trabeculectomy group of 46 patients, there were 5 failures, or 11% (2 patients with leaky cystic blebs with hypotony maculopathy that required bleb revision [1 and 3 months], 2 patients with failed blebs that required a second glaucoma procedure [Express shunts at 2 and 3 months], and 1 patient who required surgery to drain a suprachoroidal hemorrhage). There was no difference in the reoperation rate between the groups ($P = 0.74$; Tables 2 and 7).

Table 8 shows the complications seen among the 2 procedures. Hyphema was the most common complication in the canaloplasty group (21%); this was the result of blood reflux from the Schlemm canal into the anterior chamber at the end of the case. The hyphema resolved completely over a 1- to 3-week period in all patients. Peripheral anterior synechiae (PAS) formation was seen in 2 patients (6%) after canaloplasty. One patient presented with complete closure of the Descemet's window and adjacent area secondary to PAS formation leading to acute glaucoma 2 weeks after surgery. This may have resulted from a microperforation into the anterior chamber. Peripheral synechialysis was successfully

Table 3. Intraocular Pressure (IOP) for Canaloplasty and Trabeculectomy Groups: Complete Cohort Data

Time Point	Canaloplasty IOP (mmHg)	No. of Patients	Trabeculectomy IOP (mmHg)	No. Patients	P Value
Preoperatively	21.2±6.6	33	23.4±10.4	46	0.28
1 day	9.3±6.0	33	5.7±3.6	46	<0.01*
1 week	13.7±6.4	32	6.8±3.8	45	<0.001*
1 month	14.4±5.8	32	8.8±4.5	46	<0.001*
3 months	12.6±5.6	32	10.3±3.7	46	0.05*
6 months	12.1±4.0	32	11.2±4.5	43	0.40
9 months	12.9±5.1	33	11.6±3.4	39	0.18
12 months	13.8±4.9	33	11.6±4.0	46	0.03*

Data are mean values ± standard deviation.
*Statistically significant.

Table 4. Intraocular Pressure (IOP) for Canaloplasty and Trabeculectomy Groups: Excluding Surgical Failures*

Time Point	Canaloplasty IOP (mmHg)	No. of Patients	Trabeculectomy IOP (mmHg)	No. of Patients	*P* Value
Preoperatively	19.3±4.6	28	22.9±9.9	41	0.07
1 day	8.7±5.6	28	5.8±3.6	41	0.02‡
1 week	13.5±6.6	28	6.8±3.9	40	<0.001‡
1 month	12.8±3.7	28	9.0±4.5	41	<0.001‡
3 months	12.2±5.2	28	10.0±3.5	41	0.05‡
6 months	11.8±3.5	28	11.1±4.6	39	0.47
9 months	11.9±3.3	26	11.4±3.5	29	0.53
12 months	13.3±3.6	28	11.3±4.1	41	0.05‡

Data are mean values ± standard deviation.
*All IOP failures were included in the surgical failure group.
‡Statistically significant.

performed at the slit lamp using viscoelastic agent with a cannula. The peripheral synechial attachment reoccurred at the same site 1 week later, leading to elevated IOP. This patient was treated with an Ahmed glaucoma valve with good IOP control. The second patient developed a 360° angle closure over a 3-month period leading to elevated IOP. The IOP was controlled after an uneventful Express shunt operation.

One patient developed Descemet's detachment in the canaloplasty group. The study patient was found to have a large detachment filled with viscoelastic mixed with blood (Fig 2) and was managed through a stab incision to drain the entrapped blood/viscoelastic. The detachment resolved without any additional complications or detrimental effects on the VA.

Choroidal effusion was the most frequent complication in the trabeculectomy group (17%). All cases resolved without any operative intervention. One patient in the trabeculectomy group suffered suprachoroidal hemorrhage that required drainage. Seven patients (15%) required bleb revision with subconjunctival injection of MMC (0.1 cc of 0.4 mg/cc) at the slit lamp for failing blebs. Five of these patients responded well with nice bleb formation and lower IOP. Two patients failed despite needling and required further glaucoma surgery.

Discussion

Trabeculectomy remains the most widely used operative procedure in the management of open-angle glaucoma. It results in excellent long-term IOP control. However, trabeculectomy is associated with many complications, including flat or shallow anterior chamber, wound leak, hypotony, suprachoroidal hemorrhage, or choroidal effusions in the immediate postoperative period. Trabeculectomy is also associated with cataract formation, bleb-related problems such as fibrosis or encapsulation of the bleb leading to failure of the surgery, leaky cystic blebs with hypotony, decreased vision from hypotony maculopathy, and endophthalmitis.[3,4]

Canaloplasty is a new, nonpenetrating glaucoma procedure for the management of open-angle glaucoma. Canaloplasty uses the natural aqueous outflow pathways to reduce IOP. The goal of the procedure is to increase the flow of aqueous humor from the anterior chamber into the Schlemm canal by circumferential viscodilation using a flexible microcatheter and tensioning of Schlemm's canal with a 10-0 Prolene suture. The surgical results reported after canaloplasty seem to be comparable with the gold standard, trabeculectomy. Canaloplasty is reported to have fewer complications compared with standard trabeculectomy, including postoperative hypotony and choroidal effusions.[1,2] The absence of a functioning bleb means that success or failure of this surgery is independent of subconjunctival fibrosis. If canaloplasty demonstrates effective pressure control with fewer sight-threatening complications,

Table 5. Intraocular Pressure (IOP) in Canaloplasty and Trabeculectomy Groups: Excluding Surgical Failures and Patients on Postoperative Medications

Time Point	Canaloplasty IOP (mmHg)	No. of Patients	Trabeculectomy IOP (mmHg)	No. of Patients	*P* Value
Preoperatively	20.3±4.7	16	23.0±10.5	34	0.32
1 day	9.9±6.2	16	5.7±3.4	34	0.02*
1 week	12.5±7.0	16	6.4±3.4	33	<0.01*
1 month	12.2±3.3	16	8.0±4.0	34	<0.01*
3 months	11.8±5.1	16	9.6±3.1	34	0.14
6 months	11.8±3.5	16	10.5±4.6	32	0.27
9 months	12.8±4.0	16	10.5±3.1	24	0.08
12 months	13.2±3.2	16	10.7±3.7	34	0.02*

Data are mean values ± standard deviation.
*Statistically significant.

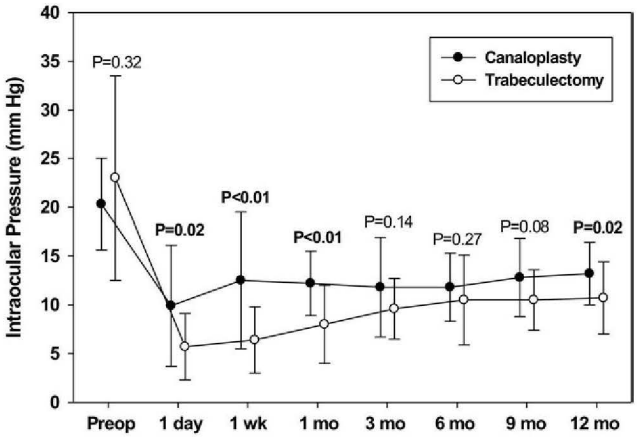

Figure 1. Comparison of mean intraocular pressure (IOP) between canaloplasty and trabeculectomy groups after excluding surgical failures and patients taking postoperative medications at 12 months. Significant mean IOP differences are shown in bold over a 12-month period.

then canaloplasty may have compelling advantages over bleb-dependent trabeculectomy with MMC.

The present study compares the surgical outcomes after canaloplasty and standard trabeculectomy in patients with open-angle glaucoma. Intraocular pressure reduction at 12 months was in the low teens in the majority of patients in both groups.

The IOP reduction as a percentage (compared with preoperative values) was somewhat greater in the patients treated by trabeculectomy compared with canaloplasty (43% vs. 32%), but this difference at 12 months was not significantly different between the 2 groups ($P = 0.072$). The trabeculectomy group achieved lower IOP (closer to 10 mmHg) with a lesser percentage of patients needing postoperative glaucoma medications at 12 months' follow-up. This might mean that physicians may want to consider trabeculectomy in patients with advanced glaucoma who may benefit from IOP closer to 10 mmHg.

The IOP results after canaloplasty are similar to previous publications. Lewis et al[1] reported on 74 patients with canaloplasty. The mean IOP was 14.5±3.0 at 12 months. Shingleton et al[2] have reported their results after canaloplasty combined with cataract surgery. The mean IOP was 13.7±4.4 at 12 months, which is very similar to the mean IOP achieved in the present study. Both of these studies were multicenter studies.

Table 7. Reoperations

	Reoperation Type (n)	No. of Patients (%)
Canaloplasty	Trabeculectomy (1) Express shunt (1) Ahmed glaucoma valve (3)	5 (15)
Trabeculectomy*	Bleb revision for leaking cystic bleb (2) Express shunt for failed blebs (2)	4 (9)

*One patient had suprachoroidal hemorrhage drainage.

The IOP results after trabeculectomy with MMC were 11.6±4.0 mmHg at 12 months in the present study. These results are similar to previous publications. Lin et al[3] reported on 32 eyes after fornix-based trabeculectomy with MMC. The IOP was 11.7±2.5 at 12 months. Fontana et al[4] reported IOP of 11.2 mmHg at 1 year after trabeculectomy with MMC. Similar results have been reported by other authors.

Visually acuity returned to baseline at similar rates in both groups. The reasons for this finding may be related to the fact that the majority of the patients did not experience serious complications in either group. The main reason for decreased vision in the immediate postoperative period in the canaloplasty group was hyphema, which resolved in all patients without intervention over 1 to 3 weeks' and in the trabeculectomy group the main reason for decreased vision was hypotony. Median postoperative medications at last follow-up was similar between the 2 groups, although the trabeculectomy group had a greater proportion of eyes on no medications.

In terms of complications, the study population experienced hypotony maculopathy (4%), choroidal effusions (17%), and suprachoroidal hemorrhage (2%) in the trabeculectomy group, whereas none of the patients in the canalo-

Table 6. Logarithm of the Minimum Angle of Resolution Visual Acuity in Canaloplasty and Trabeculectomy Groups

	Canaloplasty Group		Trabeculectomy Group		
Time Point	*Acuity*	*No. Patients*	*Acuity*	*No. Patients*	*P* Value
Preoperatively	0.54±0.62	33	0.44±0.54	46	0.44
1 day	0.96±0.71	33	0.81±0.57	46	0.33
1 week	0.62±0.54	32	0.75±0.55	45	0.34
1 month	0.50±0.46	32	0.65±0.52	46	0.22
3 months	0.48±0.54	32	0.55±0.54	46	0.62
6 months	0.48±0.55	32	0.50±0.58	43	0.90
9 months	0.52±0.58	33	0.47±0.53	39	0.72
12 months	0.47±0.50	33	0.47±0.58	46	0.98

Data are mean values ± standard deviation in logarithm of the minimum angle of resolution units.
No significant differences between the 2 groups, repeated-measures analysis of variance.

plasty group experienced these complications. This might suggest that one should consider canaloplasty in those patients who are at high risk of developing these complications, such as those with high myopia, a history of choroidal effusions in the fellow eye, and patients at risk of developing suprachoroidal hemorrhage. Lin et al[3] reported 25% choroidal effusions and a 9% failure rate after trabeculectomy. The study complication rates are comparable with the published literature.[3,4,7,8]

Hyphema (21%) was the most common postoperative complication seen in canaloplasty, and it resolved without intervention. This incidence is higher than is reported in the literature.[1,2] Most of these cases happened early in the series owing to low IOPs in the immediate postoperative period. Since then, we have been injecting balanced salt solution into the anterior chamber at the end of the surgery to increase the IOP above the episcleral venous pressure and have noticed a decrease in the incidence of hyphema.

Descemet's detachment seems to be a unique complication seen in 1% to 5% of canaloplasty patients. The detachment happens during the injection of Healon GV into the Schlemm canal. Either injection of excess amounts of Healon GV or a weak attachment/demarcation between the canal wall/Schwalbe's line and the Descemet's membrane seems to result in the detachment. In some cases, blood from the Schlemm canal can track into the detachment along with the Healon GV. Usually, these complications are self-limiting and do not need any treatment.

Peripheral synechial formation was noticed after canaloplasty in 2 patients leading to failure of the surgery. Both cases happened in the early part of the series when we used cyclopentolate 1% in the postoperative period. Since then, we have changed our protocol to pilocarpine 1%, 3 times a day, starting 3 days before surgery and continuing for 2 to 3 weeks postoperatively, to position the iris as far from the trabecular meshwork area as possible to prevent PAS formation. Since then, we have noted a significant reduction in PAS formation.

Previous studies have reported similar complications. Lewis et al[1] reported 3 patients with hyphema, 1 patient with Descemet's tear, 1 patient with hypotony, and 1 patient with choroidal effusion. Shingleton et al[2] reported hyphema in 5.6% of patients, Descemet's tear in 1.9%, and iris prolapse or peripheral synechial formation in 1.9%.

Limitations of this study include the inherent weaknesses of all retrospective studies, including possible selection bias, limited patient population, and the lack of true randomization. This study analyzed the surgical results of a single surgeon (RSA); thus, the results may not apply to everyone. However, because the 2 groups showed similar patient demographics without any baseline covariate imbalances, we believe that any confounding factors are probably minimal.

Table 8. Complications

Type of Complication	Canaloplasty (n = 33)	Trabeculectomy (n = 46)	*P* Value
Choroidal effusions	0 (0%)	8 (17%)	0.02*
Hyphema	7 (21%)	1 (2%)	<0.01*
Descemet's detachment	1 (3%)	0 (0%)	0.42
Peripheral anterior synechiae	2 (6%)	0 (0%)	0.17
Suprachoroidal hemorrhage	0 (0%)	1 (2%)	0.99
Hypotony maculopathy	0 (0%)	2 (4%)	0.50
Bleb revision with needling	0 (0%)	7 (15%)	0.03*

*Statistically significant difference between groups (Fisher's exact test).

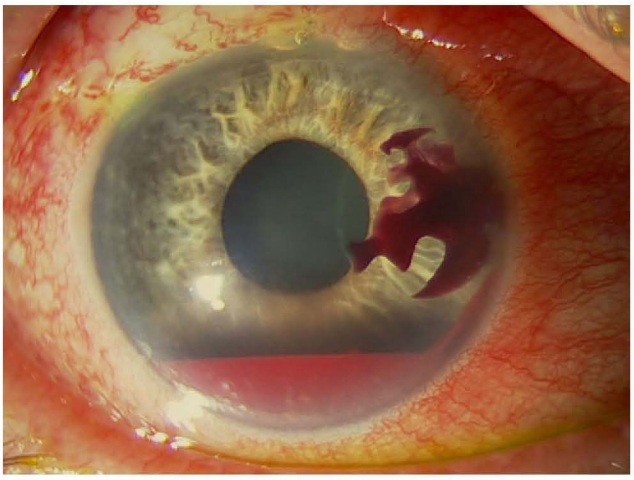

Figure 2. Shows the patient with blood/viscoelastic trapped in the Descemet's detachment after canaloplasty.

In conclusion, canaloplasty resulted in a significant reduction in the IOP into the low teens in the absence of a bleb. However, trabeculectomy with MMC resulted in significantly lower IOP (closer to 10 mmHg) as well as a lower percentage of patients requiring postoperative medications. These results need to be confirmed by a prospective, randomized, longitudinal study.

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Footnotes and Financial Disclosures

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EXHIBIT 8

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GLAUCOMA

Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results

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Abstract
Background To report 3-year results investigating the safety and efficacy of canaloplasty, a procedure involving circumferential viscodilation of Schlemm's canal and tensioning of the inner canal wall to treat open-angle glaucoma.
Methods This was a prospective, multi-center, interventional study of 109 eyes of 109 adult, open-angle glaucoma patients undergoing canaloplasty or combined cataract-canaloplasty surgery. Qualifying preoperative intraocular pressures (IOP) were at least 16 mmHg with historical IOPs of at least 21 mmHg with or without medical therapy. A flexible microcatheter was used to viscodilate the full circumference of the canal and to place a trabecular tensioning suture. Primary outcome measures included IOP, glaucoma medication usage, and adverse events.
Results Eyes with canaloplasty showed a mean baseline IOP of 23.0±4.3 mmHg and mean glaucoma medication usage of 1.9±0.7 medications, which decreased to a mean IOP of 15.1±3.1 mmHg on 0.9±0.9 medications at 3 years postoperatively. Eyes with combined cataract-canaloplasty surgery showed a mean baseline IOP of 24.3±6.0 mmHg on 1.5±1.2 medications, which decreased to a mean IOP of 13.8±3.2 mmHg on 0.5±0.7 medications at 3 years. Intraocular pressure and medication use results for all study eyes were significantly decreased from baseline (p <0.00001) at all intervals. Late postoperative complications included cataracts (19.1%) and transient IOP elevation (1.8%).
Conclusions Canaloplasty demonstrated significant and sustained IOP reductions accompanied by an excellent short- and long-term safety profile in adult patients with open-angle glaucoma.

Keywords Canaloplasty · Microcatheter · Non-penetrating glaucoma surgery · Open-angle glaucoma · Schlemm's canal

Clinical trial registration site and number: http://www.controlled-trials.com/ISRCTN12425531; ISRCTN12425531

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Introduction

The surgical treatment of the natural aqueous outflow system for the management of open-angle glaucoma may minimize potentially severe complications associated with traditional filtering surgery by avoiding entry into the anterior chamber [1]. Elements common to such non-penetrating procedures such as deep sclerectomy with and without implant [2, 3], viscocanalostomy [4], and canaloplasty [5], involve the dissection of a superficial and deep scleral flap to create an intrascleral lake and a Descemet's window. In principle, aqueous can then bypass the presumably higher resistance of the trabecular meshwork by flowing through Descemet's window into the intrascleral

lake. In viscocanalostomy, aqueous within the lake may then re-enter the natural outflow system through adjacent surgically created ostia in Schlemm's canal. In contrast to deep sclerectomy, viscocanalostomy intends to route the aqueous through the canalicular outflow system without a subconjunctival bleb.

Canaloplasty extends the principles of non-penetrating glaucoma surgery by allowing surgeons to viscodilate Schlemm's canal along its entire length using a flexible microcatheter [5]. The placement of an intracanalicular tension suture within Schlemm's canal distends the full circumference of the trabecular meshwork inward to maintain an open canal. The two reconstructive steps in Schlemm's canal in combination with a water-tight surgical closure result in a non-bleb-dependent surgical treatment for glaucoma. Prior studies have reported on 1-, 2-, and 3-year results from prospective clinical trials of canaloplasty, which showed significant reductions in IOP and glaucoma medication usage in conjunction with an excellent safety profile [6–9]. The 3-year study results reported herein describe the long-term safety and efficacy of canaloplasty.

Materials and methods

Study design

This paper reports the 3-year results of a multicenter, prospective, single-arm study of canaloplasty at three clinical sites in Germany involving four surgeon investigators. This research was conducted in accordance with the principles set forth in the 1964 Declaration of Helsinki, ISO 14155–1, and the International Conference on Harmonization Good Clinical Practice. The protocol was approved for each study site by an Ethics Committee and all patients provided informed consent prior to their inclusion in the study. All enrollees underwent a complete baseline ophthalmic examination, which included the ocular history, ophthalmic and systemic medication usage, best-corrected visual acuity (BCVA), IOP by unmasked Goldmann applanation tonometry, slit-lamp examination, central corneal thickness, gonioscopy, and a fundus examination. Follow-up examinations were conducted at 1 day, 1 week, and 1, 3, 6, 12, 18, 24, 30, and 36 months.

Patient selection

All patients were at least 18 years old at the time of enrollment, able to understand and provide informed consent, and were scheduled for glaucoma surgery or combined cataract and glaucoma surgery. Inclusion criteria for this study included a diagnosis of primary open-angle glaucoma (POAG), pigmentary glaucoma, or exfoliative glaucoma, and a baseline and most recent IOP of 16 mmHg or higher and a historical IOP of 21 mmHg or higher. With many patients on maximally tolerated medical therapy, the protocol was designed to allow patients to withdraw from medications due to intolerance or poor compliance provided they had a historical IOP ≥21 mmHg. All patients had documented visual field loss, were in various stages of the disease, and met the individual criteria of each surgeon for the diagnosis of glaucoma and failure of prior medical or laser therapy. Exclusion criteria included neovascular disease, uveitis, peripheral anterior synechiae, angle recession, developmental or secondary glaucoma with the exception of pigmentary and exfoliative glaucoma, previous ocular surgeries that would interfere with complete circumferential catheterization of Schlemm's canal, and more than two laser trabeculoplasty procedures. Only one eye per patient was eligible.

All patient enrollment and examination case report forms were verified against the original medical records by study monitors. Data which received 100% source data verification included all baseline data including inclusion and exclusion criteria; key efficacy and safety variables such as IOP, number of glaucoma medications, secondary procedures, and adverse events, and all patients who had early termination from study participation.

Treatment

Following a non-penetrating, two-flap dissection technique to expose Schlemm's canal and create an intrascleral lake and a Descemet's window, a flexible microcatheter (iTrack™ 250A, iScience Interventional Corporation, Menlo Park, CA, USA) was used to dilate the full circumference of the canal by injecting Healon GV (Abbott Medical Optics, Santa Ana, CA, USA) during catheterization. The microcatheter has a 200-µm-diameter shaft with an atraumatic distal tip of approximately 250 µm in diameter, a lumen through which the viscoelastic is delivered, and illumination near the tip so that the surgeon can guide the microcatheter by observing the beacon transsclerally. A Descemet's window was formed just prior to catheterization of the canal. Following circumferential catheterization, a 10–0 prolene suture (Ethicon Inc., Somerville, NJ, USA) was tied to the microcatheter tip and the device was withdrawn pulling the suture into the canal. The suture was cut from the microcatheter and then tied in a loop encircling the inner wall of Schlemm's canal. The suture loop was tightened to distend the trabecular meshwork inwards placing the tissues in tension and then locking knots were added. The superficial scleral flap was then sutured watertight with a minimum of five sutures to avoid bleb formation.

The post-surgical medication regimen consisted of non-steroidal anti-inflammatory drugs such as ketorolac tromethamine (Acular, Allergan Inc., Irvine, CA, USA) four times per day used for up to 4 weeks; prednisolone acetate (Pred Forte, Allergan Inc.) four times per day with tapering for up to 4 weeks, and an antibiotic such as gentamicin three times per day for a week or as needed. During the course of the study, surgeons were allowed to intervene with medical or interventional therapy as they deemed necessary.

Data analysis

The efficacy analysis was stratified according to the treatment received and the results of different groups of patients were evaluated. Group 1 included all patients with successful suture placement during canaloplasty alone and group 2 included all patients with successful suture implantation during canaloplasty combined with cataract surgery. The primary endpoints evaluated included mean IOP and mean number of glaucoma medications at each follow-up visit. Combination glaucoma medications were enumerated as individual medications in this study. The secondary endpoints included surgical and post-surgical complications and secondary interventions.

Baseline characteristics were compared between surgical groups using the Pearson Chi-square test for categorical variables such as gender, race, OD/OS eyes, previous surgery, and diagnosis and analysis of variance (ANOVA) for IOP, visual acuity (logMAR units), and number of glaucoma medications [10]. For each of the three groups, repeated-measures ANOVA using a mixed-model approach for longitudinal data was applied to assess changes from baseline in IOP, acuity, and medications with Bonferroni adjusted p values for assessing group differences [11]. When comparing groups 1 and 2, age, baseline IOP, and medications were included as covariates to control for possible confounding with the group-by-time interaction. F test for comparing slopes between groups from baseline through 36 months and differences in IOP, medications, and visual acuity was performed at specific time points. A compound symmetry covariance structure was used to handle the repeated measurements for the same patients at different time points. Two-tailed values of $p \leq 0.05$ were considered statistically significant with adjustment for multiple comparisons as appropriate. The SPSS statistical package was used for analysis of the data (version 18.0, SPSS Inc./IBM, Chicago, IL, USA).

Results

Demographics

All intent-to-treat eyes consisted of 109 eyes of 109 patients at baseline with 96 eyes (88.1%) completing the 3-year visit. Of the remaining 13 subjects, five (4.6%) were lost to follow-up, four (3.7%) underwent additional glaucoma surgery, three (2.8%) withdrew from the study for personal reasons, and one (0.9%) was terminated as the subject was later found not to have met the inclusion criteria.

Table 1 shows the demographics for the study group. The successful placement of a tensioning suture into Schlemm's canal was achieved in 98 eyes (89.9%). No significant adverse events occurred due to failure to fully catheterize the canal. Ninety-three eyes (85.3%) had canaloplasty only with or without tensioning suture placement and 16 eyes (14.7%) with visually significant cataracts underwent canaloplasty combined with cataract extraction (phacocanaloplasty), all with successful suture placement.

Change in intraocular pressure and glaucoma medication usage

Table 2 and Fig. 1 show the efficacy results for group 1 (canaloplasty with successful suture placement) and group 2 (phacocanaloplasty with successful suture placement). Three years postoperatively, group 1, consisting of eyes receiving canaloplasty alone with successful suture implantation, attained a 34.3% reduction in IOP. At baseline, two of 82 eyes (2.4%) were not on medical therapy and 14 eyes (17.1%) were on three or more medications in comparison to 31 of 74 eyes (41.9%) taking no medical therapy and three eyes (4.1%) on three or more medications at 3 years. IOP and medication use were significantly decreased from baseline ($p<0.00001$) at all time points.

For the 11 eyes that had canaloplasty only, without suture placement, the mean baseline IOP was 24.4±5.5 mmHg on 1.9±1.2 medications, decreasing to a mean IOP of 15.6±3.6 mmHg on 1.2±0.7 medications ($n=9$), representing a 36.1% reduction in IOP at 3 years. The mean IOP at 36 months was lower in group 1, which had successful suture placement. Although the IOP for these 11 eyes was significantly decreased from baseline ($p<0.01$) at all time points, the sample size of this group was too small for meaningful statistical comparison to group 1.

Further analysis of group 1 (canaloplasty only with suture placement) included evaluating the effects of inadvertent intraoperative perforations of Descemet's window or the inner wall of Schlemm's canal and of postoperative neodymiun:YAG (Nd:YAG) goniopuncture. Of the seven of 82 (8.5%) eyes that had intraoperative perforations, the mean baseline IOP was 23.6±4.5 mmHg on 2.0±0.0 glaucoma medications decreasing to 14.0±1.4 mmHg on 0.8±0.8 medications at 36 months, similar to outcomes of other eyes in group 1. None of these seven eyes had an IOP less than 10 mmHg at any interval. These

Table 1 Study group demographics of all intent-to-treat eyes

Parameter	Value
Enrollees/eyes, *n*	109
Age in years	
Mean±SD	67.3±9.9
Range	41.1–86.9
Sex, *n* (%)	
Female	55 (50.5)
Male	54 (49.5)
Race, *n* (%)	
White	108 (99.1)
Black	1 (0.9)
Glaucoma diagnosis, *n* (%)	
Primary open-angle	101 (92.7)
Pseudoexfoliative	6 (5.5)
Mixed mechanism	1 (0.9)
Pigmentary dispersion	1 (0.9)
Previous ocular surgery, *n* (%)	
Cataract	20 (18.3)
Viscocanalostomy	12 (11.0)
Laser peripheral iridotomy	5 (4.6)
Laser trabeculoplasty	4 (3.7)
Nd:YAG capsulotomy	1 (0.9)
Cyclophotocoagulation	1 (0.9)
Successful placement of intracanalicular suture, *n* (%)	98 (89.9)
Combined cataract procedure (phacocanaloplasty), *n* (%)	16 (14.7)

n sample size; *POAG* primary open-angle glaucoma; *Nd:YAG* neodymium YAG

perforations occurred throughout the duration of the study and were not apparently related to a learning curve effect or to differences between surgeons. Of the seven of 82 (8.5%) eyes that had postoperative goniopuncture, the mean baseline IOP was 23.6±2.0 mmHg on 2.1±0.7 glaucoma medications, decreasing to 18.2±2.5 mmHg on 1.5±0.5 medications at 36 months, which was higher than outcomes of other eyes in group 1.

Group 2, consisting of eyes having canaloplasty with successful suture placement combined with phacoemulsification, showed a 43.2% reduction in IOP at 3 years. At baseline, 3 of 16 eyes (18.8%) were on no medical therapy and three eyes were on three or more medications in comparison to eight of 13 eyes (61.5%) on no medical therapy and no eyes on three more medications at 3 years. IOP and medication use results were significantly decreased from baseline ($p<0.00001$ and $p<0.006$, respectively) at all time points. Postoperative IOP was lower in group 2 (phacocanaloplasty) than group 1 (canaloplasty alone) at all time points, but this difference was not statistically significant ($p=0.22$ at 3 years).

Visual acuity results

Snellen best-corrected visual acuities were converted to logarithm of the minimal angle of resolution (logMAR) equivalents for the purpose of data analysis. At 3 years, eyes in group 1 (canaloplasty alone), which had a mean baseline LogMAR of 0.22±0.25 and a LogMAR of 0.20±0.26 at 3 years, demonstrated no significant change from baseline values ($p=0.70$).

Success results

The success results for this study are presented in Table 3 and stratify the absolute IOP readings by the percentage of eyes with values of at least 21, 18, or 15 mmHg for group 1 (canaloplasty alone with suture placement) and group 2 (phacocanaloplasty with suture placement). A complete success is defined as reaching the specified IOP without glaucoma medication and a qualified success is defined as including the use of one or two medications. At 3 years, 36.5% of group 1 eyes attained an IOP of ≤18 mmHg with no medications and 82.4% achieved a qualified success. In

Table 2 Outcome results

Exam	Group 1 (Canaloplasty alone)			Group 2 (Phacocanaloplasty eyes)		
	n	Mean IOP in mmHg±SD	Mean medications±SD	*n*	Mean IOP in mmHg±SD	Mean medications±SD
Baseline	82	23.0±4.3	1.9±0.7	16	24.3±6.0	1.5±1.2
3 months	70	15.6±3.6	0.4±0.7	13	13.7±4.7	0.2±0.4
6 months	65	15.8±3.2	0.4±0.7	13	12.8±3.0	0.1±0.3
12 months	73	15.5±3.5	0.6±0.9	15	14.0±3.7	0.1±0.4
18 months	67	15.4±3.5	0.7±0.9	8	13.9±3.5	0.3±0.5
24 months	70	15.4±3.3	0.7±0.8	12	14.7±2.8	0.3±0.5
30 months	67	15.7±4.3	0.8±0.8	11	14.5±3.6	0.3±0.6
36 months	74	15.1±3.1	0.9±0.9	13	13.8±3.2	0.5±0.7

n sample size; IOP intraocular pressure; *SD* standard deviation

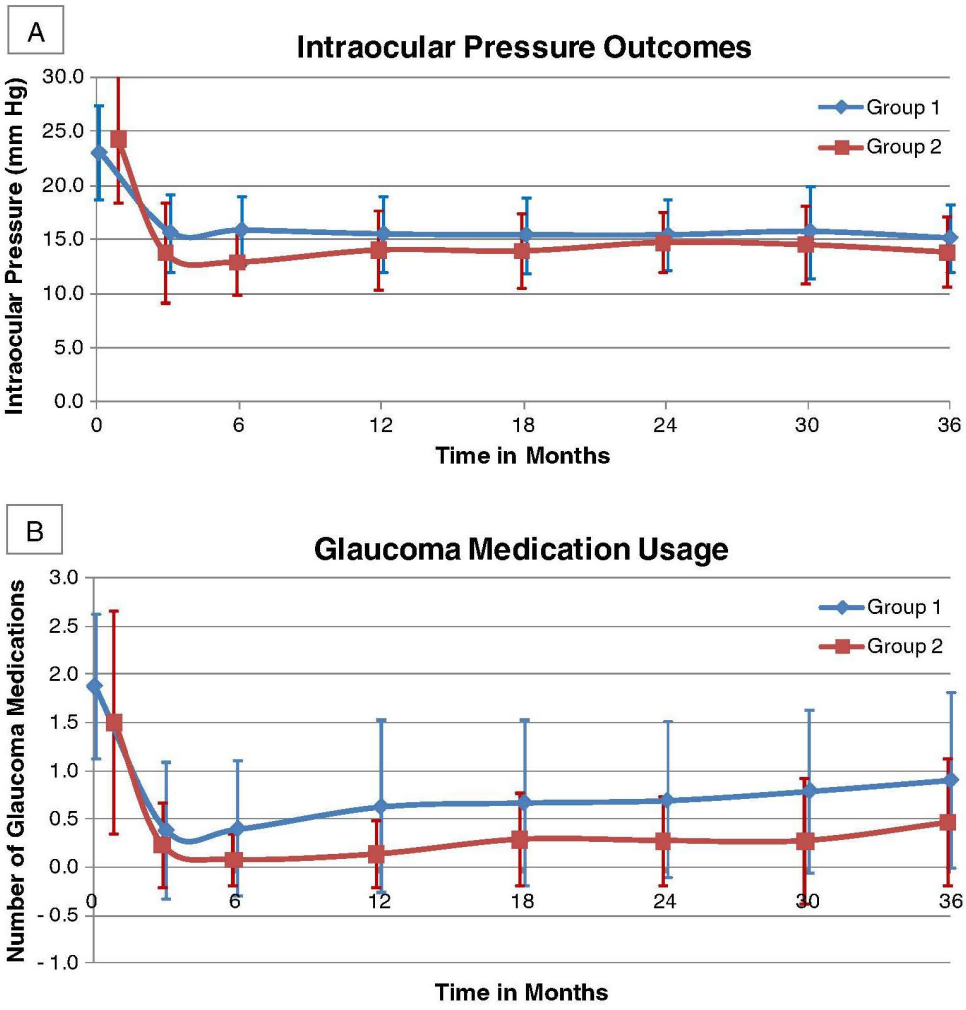

Fig. 1 Graph comparing efficacy outcomes of group 1 (canaloplasty alone with successful suture placement) and group 2 (combined cataract-canaloplasty eyes with successful suture placement). **a** The *top graph* presents the intraocular pressure results through 36 months. **b**The *bottom graph* shows the glaucoma medication usage through 36 months. The *bars* represent 1 standard deviation

group 2, 61.5% of eyes achieved an IOP of ≤18 mmHg with no medications and 100.0% achieved a qualified success. Postoperative interventions and patient attrition would make these percentage figures in actual clinical practice less than stated. In Fig. 2, specific IOP results at 3 years postoperatively as compared to baseline for each eye are presented graphically in a scatter plot for groups 1 and 2. Figure 3 shows Kaplan–Meier survival plots for cumulative failure rates of groups 1 and 2 using failure criteria of an IOP >18 mmHg on two consecutive visits. The Chi-square approximations for logrank and Wilcoxon tests comparing the failure proportions of groups 1 and 2 did not demonstrate a significant difference in cumulative failure rate ($p<0.27$).

Table 3 Success results at 12, 24, and 36 months for group 1 (canaloplasty only) and group 2 (phacocanaloplasty)

	Group 1			Group 2		
	12 months	24 months	36 months	12 months	24 months	36 months
Unqualified success						
≤ 21 mmHg	58.9%	47.8%	40.5%	86.7%	72.7%	61.5%
≤ 18 mmHg	50.7%	42.0%	36.5%	86.7%	63.6%	61.5%
≤ 15 mmHg	37.0%	24.6%	21.6%	73.3%	45.5%	30.8%
Qualified success						
≤ 21 mmHg	95.9%	97.1%	98.6%	93.3%	100.0%	100.0%
≤ 18 mmHg	76.7%	81.4%	82.4%	93.3%	91.7%	100.0%
≤ 15 mmHg	52.1%	51.4%	56.8%	73.3%	66.7%	69.2%

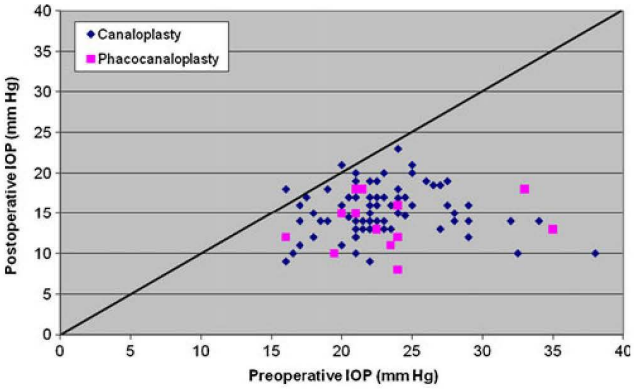

Fig. 2 Scatter plot of preoperative IOP after 36 months for group 1 (canaloplasty only with successful suture placement) and group 2 (phacocanaloplasty or combined cataract-canaloplasty with successful suture placement). Each point represents one eye showing the preoperative IOP value on the *x*-axis and the 36-month postoperative IOP on the *y*-axis. Points falling below the oblique line (which represents no change) are lower than the preoperative readings

Surgical and post-surgical complications

Table 4 shows all ocular-related surgical and postoperative complications reported regardless of severity. Most complications occurred intraoperatively or in the early postoperative phase (≤ 90 days postoperatively). During the early postoperative period, hyphema was observed in six of 109 eyes (5.5%), all resolving by the 1-week visit with the exception of one eye (0.9%), which resolved by 1 month. Microhyphema, defined as circulating red blood cells without layered blood in the anterior chamber, was observed in 14 eyes (12.8%). Six eyes (5.5%) had IOP elevation ≥30 mmHg. The IOP rises were transient and resolved by the next scheduled follow-up visit with the exception of one case (0.9%), which received cyclophotocoagulation. Descemet's membrane detachments without involvement of the visual axis occurred in four eyes (3.7%), all resolving by the next scheduled visit with the exception of one eye which resolved by 6 months postoperatively. There were no instances of hypotony defined as IOP ≤5 mmHg with shallow or flat anterior chambers.

During the late-postoperative period (> 90 days postoperatively), two of 109 eyes (1.8%) experienced an IOP elevation ≥30 mmHg. One instance of elevated IOP was successfully managed with glaucoma medical therapy. The other eye underwent cyclophotocoagulation at 27 months after experiencing an IOP elevation when medical therapy was inadvertently not administered during hospitalization for non-study related reasons. No eyes were reported to have blebs at 3 years.

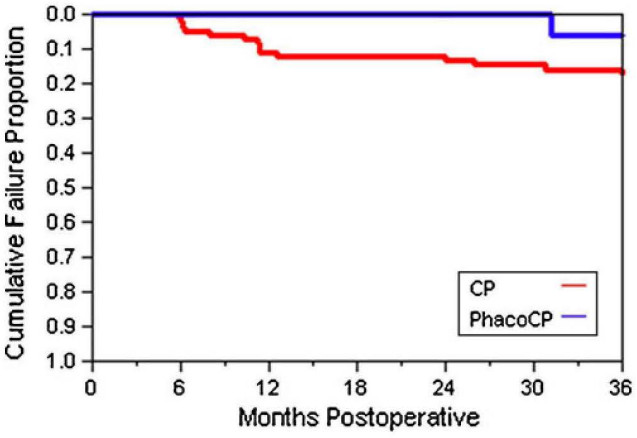

Fig. 3 Kaplan–Meier plot of the cumulative probability of failure for group 1 (CP or canaloplasty only with successful suture placement) and group 2 (PhacoCP or combined cataract-canaloplasty eyes with successful suture placement). Failure was defined as an IOP> 18 mmHg on two consecutive visits

Postoperative interventions

Table 5 includes all postoperative interventions, defined as any procedure or process undertaken following surgery with the goal of enhancing the success of the surgical outcome [12]. The most commonly performed procedures included cataract extraction (19.1% of phakic eyes) followed by Nd:YAG goniopuncture (8.3%), Nd:YAG capsulotomy (7.3%), and conjunctival suture replacement (7.3%). Five of the 17 patients receiving cataract extraction during the 3-year postoperative period were identified as having significant pre-existing cataracts prior to canaloplasty. The surgeons in these cases chose to perform cataract surgery at some point following canaloplasty. Patients who received additional glaucoma surgery including trabeculectomy, cyclophotocoagulation, and repeat canaloplasty were excluded from further analysis following these reoperations.

Discussion

The desire to improve incisional glaucoma procedures has been motivated by the need to achieve long-term intraocular pressure control in the safest possible manner. Canaloplasty obviates the need for a subconjunctival filtering bleb, which shunts aqueous to non-physiological routes. This non-filtering, bleb-free procedure restores the natural trabeculo-canalicular outflow system by circumferentially catheterizing, viscodilating, and suture tensioning the entire length of Schlemm's canal with the use of a flexible microcatheter. The 3-year results reported here reveal significant and sustained pressure lowering accompanied by a low incidence of late-postoperative complications.

Although it is difficult to compare results from studies with differing study designs and patient populations, canaloplasty

Table 4 Ocular-related surgical and post-surgical complications of all intent-to-treat eyes

Surgical/early postoperative complications (≤ 90 days post-op)	*n* (%)
Microhyphema: < 1.0 mm layered blood	14 (12.8%)
Hyphema: ≥ 1.0 mm layered blood	6 (5.5%)
Elevated intraocular pressure	6 (5.5%)
Descemet's membrane detachment	4 (3.7%)
Hypotony: IOP ≤5 mmHg with shallow anterior chamber	0
Flat/shallow anterior chamber	0
Late Postoperative Complications (> 90 days post-op)	
Cataracts	17 of 89 (19.1%)
Elevated intraocular pressure	2 (1.8%)
Blebs at 36 months	0
Endophthalmitis	0
Choroidal effusion	0
Hypotony: IOP ≤5 mmHg with shallow anterior chamber	0

n sample size; *mm* millimeter

efficacy results are comparable to the lowest IOPs achieved in non-penetrating glaucoma surgery including viscocanalostomy [13–15], deep sclerectomy with various implants [16, 17], and deep sclerectomy with adjunctive mitomycin C [18, 19]. There is some rationale to believe that the addition of circumferential viscodilation and the trabecular meshwork tensioning suture in canaloplasty may provide an additional IOP lowering effect compared to the creation of a scleral lake and a Descemet's window alone, as is often achieved with deep sclerectomy or viscocanalostomy. To our knowledge, the only study directly comparing canaloplasty to another non-penetrating procedure did indeed retrospectively reveal a significant difference in postoperative IOP and medication use at 3 years in favor of patients who received canaloplasty as compared to patients who underwent viscocanalostomy [20]. In a study by Lewis et al. [8], which reported 3-year results of canaloplasty in an international, 15-site study, outcomes of eyes were highly comparable to outcomes reported for this study. For eyes having canaloplasty alone with suture placement, Lewis reported a mean IOP of 23.5±4.5 mmHg on 1.9±0.8 medications decreasing to 15.5±3.5 mmHg on 0.9±0.9 medications at 36 months. For phacocanaloplasty eyes with suture placement, the mean IOP was 23.5±5.2 mmHg on 1.5±1.0 medications decreasing to 13.6±3.6 mmHg on 0.3±0.5 medications at 36 months.

Table 5 Postoperative Interventions for all intent-to-treat eyes

Surgical	Number (%)
Cataract surgery	17 of 89 (19.1%)
Trabeculectomy	1 (0.9%)
Canaloplasty	1 (0.9%)
Tube shunt	0
Laser	
Nd:YAG goniopuncture	9 (8.3%)
Nd:YAG capsulotomy	8 (7.3%)
Cyclophotocoagulation	3 (2.8%)
Peripheral laser iridotomy	1 (0.9%)
Iridoplasty	1 (0.9%)
Synechialysis	1 (0.9%)
Selective laser trabeculoplasty	0
Other procedures	
Conjunctival suture replacement	8 (7.3%)
Pars plana steroid injection (for central retinal vein occlusion)	1 (0.9%)

Nd:YAG neodymium-YAG

The frequency of acute and late postoperative complications was also low, and compares favorably to trabeculectomy. Early complications included a 12.8% incidence of microhyphema and a 5.5% incidence of hyphema. Following canaloplasty, it is not uncommon to observe a small amount of blood in the anterior chamber, which likely occurs when the IOP decreases to less than episcleral venous pressure. No eye in this study exhibited hypotony or flat/shallow anterior chambers. In comparison, the incidence of hyphema following trabeculectomy is reported in the range of 4–43% [18, 21–23] hypotony is reported in the range of 10–42% [20–22, 24] and flat/shallow anterior chambers are reported with an incidence of 13–43% [18, 21, 22].

Late complications following canaloplasty were infrequent, and only included elevated IOP (1.8% of eyes) and cataracts (19.1% of phakic eyes) potentially related to the procedure or due to age-related progression; 29.4% of the eyes with cataracts had significant pre-existing cataracts. For those eyes that did not have significant pre-existing cataracts, the mean length of time to postoperative cataract extraction was 23.5 months. Only 6.4% of eyes in this study experienced a 2 or more line loss of visual acuity, none of which was directly attributable to the canaloplasty procedure.

Subconjunctival bleb formation has often been classified as a postoperative complication in non-filtering glaucoma surgery [4, 25, 26]. In this canaloplasty study, no blebs were present at 3 years, and there were no reports of the postoperative complications related to blebs. No antimetabolites were used, as they have their own inherent risks. As canaloplasty is not dependent upon external filtration, immediate postoperative care does not necessitate bleb manipulations to enhance flow, such as massage, laser suture lysis, needling, and subconjunctival injections of anti-metabolites, which are often required after trabeculectomy [27].

Traditionally, safety concerns have often posed a barrier to earlier incisional glaucoma surgery, particularly in regards to the potential vision-threatening complications associated with trabeculectomy. However, the distal collector system may have a better chance of survival if intervention is undertaken earlier in the disease process, before the outflow system collapses or before chronic topical medical therapy negatively impacts the tissues [28, 29]. The excellent safety profile of canaloplasty or other non-penetrating surgery may make such procedures an earlier option in many instances, such as in younger patients where cataract formation is of concern, where medical therapy has proven insufficient, or the conjunctiva is not suitable for bleb formation. A non-filtering, bleb-independent procedure such as canaloplasty can also be offered to patients where complications cannot be tolerated, such as single-eyed patients, patients with high myopia, and patients with tubular visual fields [30].

The incidence of Descemet's membrane perforations, suggested as an indicator of an individual surgeon's experience in non-penetrating techniques [31], occurred in only 3.4% of eyes in this study and did not appear to be related to a learning curve effect as all surgeons were experienced in nonpenetrating glaucoma surgery. Should a macroperforation with iris prolapse occur, conversion to a fully penetrating procedure was not required. A canaloplasty was still performed with the addition of miochol, a peripheral iridectomy, and any additional procedures needed to reverse or prevent a subsequent iris prolapse. Eyes with Descemet's membrane perforations had similar outcomes to eyes without perforations and did not display an increased incidence of hypotony, although the number of perforations was too small to meaningfully evaluate a statistically significant effect of perforation on IOP.

Failure to place a tensioning suture into Schlemm's canal was similarly unpredictable, occurring in approximately 10% of eyes, and was often related to the microcatheter tip consistently entering a particular collector channel ostium, preventing further advancement. Complete circumferential catheterization was often successful after encountering an initial obstacle by either catheterizing in the opposite direction or by exerting pressure over the presumed collector channel ostia with a second instrument to prevent the microcatheter tip from deviating from its intended course. No significant adverse events occurred due to failure to fully catheterize the canal. Eyes without a tensioning suture were viscodilated to the fullest extent possible by catheterizing the canal from both ostia, and did not display a statistically significant difference in IOP compared to eyes with a tensioning suture, although the sample size was too small for meaningful comparison.

Combined cataract surgery with canaloplasty appears to be adjunctive. At 3 years postoperatively, the subset of eyes undergoing primary cataract surgery in conjunction with canaloplasty surgery demonstrated a lower IOP as compared to eyes undergoing canaloplasty alone. Removal of the crystalline lens could potentially improve outflow by further increasing trabecular meshwork tensioning in conjunction with canaloplasty. Other studies investigating non-penetrating glaucoma surgery in combination with phacoemulsification cataract surgery are supportive of this combined beneficial effect [32–36].

This multicenter, prospective clinical trial provides further evidence of the significant IOP lowering efficacy of canaloplasty, with continued control through a 3-year postoperative period. The risk profile of canaloplasty was favorable and consistent with the well-documented, lower risks associated with other non-penetrating procedures. Predictive factors for successful canaloplasty outcomes and reasons for later failure remain unclear and should be explored in future studies.

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Conflict of Interest Dr. Tetz acknowledges a consulting agreement with iScience Interventional Corporation. Dr. Koerber, Dr. von Wolff, and Dr. Bull have no conflicting interests to disclose.

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EXHIBIT 9

ARTICLE

Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma

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PURPOSE: To report 3-year results of the safety and efficacy of canaloplasty, a procedure involving circumferential viscodilation and tensioning of the inner wall of Schlemm canal to treat open-angle glaucoma.

SETTING: Multicenter surgical sites.

DESIGN: Nonrandomized multicenter clinical trial.

METHODS: This study comprised adult open-angle glaucoma patients having canaloplasty or combined cataract–canaloplasty surgery. Qualifying preoperative intraocular pressures (IOPs) were at least 16 mm Hg with historical IOPs of at least 21 mm Hg. A flexible microcatheter was used to viscodilate the full circumference of the canal and to place a trabecular tensioning suture. Primary outcome measures included IOP, glaucoma medication use, and adverse events.

RESULTS: Three years postoperatively, all study eyes (n = 157) had a mean IOP of 15.2 mm Hg ± 3.5 (SD) and mean glaucoma medication use of 0.8 ± 0.9 compared with a baseline IOP of 23.8 ± 5.0 mm Hg on 1.8 ± 0.9 medications. Eyes with combined cataract–canaloplasty surgery had a mean IOP of 13.6 ± 3.6 mm Hg on 0.3 ± 0.5 medications compared with a baseline IOP of 23.5 ± 5.2 mm Hg on 1.5 ± 1.0 medications. Intraocular pressure and medication use results in all eyes were significantly decreased from baseline at every time point ($P<.001$). Late postoperative complications included cataract (12.7%), transient IOP elevation (6.4%), and partial suture extrusion through the trabecular meshwork (0.6%).

CONCLUSION: Canaloplasty led to a significant and sustained IOP reduction in adult patients with open-angle glaucoma and had an excellent short- and long-term postoperative safety profile.

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Underlying the growing interest in Schlemm canal surgery is the desire to achieve a beneficial reduction in intraocular pressure (IOP) without the complications associated with trabeculectomy.[1,2] Trabeculectomy is the standard against which all other forms of glaucoma surgery are compared due to its long-standing proven ability to lower IOP.[3–5] Trabeculectomy involves the creation of a fistula in the anterior chamber, allowing aqueous humor to drain through a subconjunctival filtering bleb. Of concern is that penetration of the intraocular space is associated with well-established immediate and long-term risks, including intraoperative and postoperative bleeding, shallow anterior chamber, hypotony, choroidal detachment, cataract formation, suprachoroidal hemorrhage, and bleb-related endophthalmitis.[6–10]

Nonfiltering techniques obviate the need for a subconjunctival filtering bleb, which shunts aqueous to nonphysiologic routes. Canaloplasty intends to restore the natural trabeculocanalicular outflow system by

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circumferentially catheterizing and viscodilating Schlemm canal along its entire length with the use of a flexible microcatheter.[11] The placement of an intracanalicular tension suture within Schlemm canal distends the trabecular meshwork inward, stenting the canal open.

Previously, Lewis et al.[12,13] reported 1-year and 2-year interim results in this multicenter prospective clinical study of canaloplasty in adults with open-angle glaucoma. In those papers, canaloplasty yielded a significant reduction in IOP and antiglaucoma medication use with few surgical complications. This 3-year analysis addresses the longevity of treatment safety and efficacy, a key consideration in the treatment of any chronic disease.

PATIENTS AND METHODS

Study Design

This is the 3-year report of an international multicenter prospective open-label interventional study of canaloplasty at 15 clinical sites in the United States and Germany involving 18 surgeon investigators. This research was performed in accordance with the principles set forth in the Declaration of Helsinki, the Regulations and Guidelines of the U.S. Food and Drug Administration, International Organization for Standardization 14155-1, and the International Conference on Harmonization Good Clinical Practices. This study was designed to show the safety and efficacy of the canaloplasty procedure in reducing IOP in nonfiltering surgery for the treatment of open-angle glaucoma. The protocol was approved for each study site by the appropriate institutional review board (IRB) or ethics committee (EC), and all patients provided informed consent before having any study-related procedure. Due to the encouraging results in the initial study with 1-year follow-up, all enrollees were asked to complete an additional IRB/EC-approved patient consent for extended follow-up at 6-month intervals for an additional 2 years. Details of the study methods have been described in the interim papers.[12,13]

All enrollees had a complete baseline ophthalmic examination that included the ocular history, ophthalmic and systemic medication use, corrected distance visual acuity (CDVA), IOP by Goldmann applanation tonometry, slitlamp evaluation, central corneal thickness, gonioscopy, and a fundus examination. Snellen CDVA values were converted to logMAR equivalents for data analysis. Follow-up examinations were performed at 1 day, 1 week, and 1, 3, 6, 12, 18, 24, 30, and 36 months, and all relevant information was recorded, including ophthalmic medications, CDVA, IOP, slitlamp examination, gonioscopy, fundoscopy, and adverse event and secondary procedure reporting. High-resolution ultrasound biomicroscopy (UBM) images (iUltrasound, iScience Interventional Corp.) of the anterior angle and Schlemm canal were captured preoperatively, intraoperatively, and postoperatively to assess viscodilation of Schlemm canal (Figure 1), distension of the trabecular meshwork due to the tensioning suture, and the size of the surgically created Descemetic window. Anterior segment imaging relating postsurgical anterior segment morphology with IOP-lowering efficacy will be addressed in a future report.

Patient Selection

The study protocol allowed flexibility in patient selection and treatment options to reflect each investigator's current practice of glaucoma surgery. Specifically, the protocol allowed phacoemulsification with posterior chamber intraocular lens implantation in combination with canaloplasty and previous surgeries that would not interfere with complete circumferential catheterization of Schlemm canal. All patient enrollment and examination case report forms were verified against the original medical records by study monitors. Data that received 100% source data verification included all baseline data including inclusion and exclusion criteria; key efficacy and safety variables, such as IOP, number of glaucoma medications, secondary procedures, and adverse events; and all patients who had early termination from study participation. All treated eyes were enrolled in the study, and no roll-in or practice eyes were excluded. Eyes that did not meet enrollment criteria were excluded from this analysis, but the patients were followed for complications.

All patients were at minimum 18 years of age at the time of enrollment, able to understand and provide informed consent, and were scheduled for glaucoma surgery or combined cataract and glaucoma surgery. Inclusion criteria for this study included a diagnosis of primary open-angle glaucoma (POAG), pigmentary glaucoma, exfoliative glaucoma, or POAG mixed with another included mechanism and a baseline IOP of 16 mm Hg or higher taken, at most, 60 days before surgery, and a historical IOP of 21 mm Hg or higher. With many patients on maximally tolerated medical therapy, the protocol was designed to allow patients to withdraw from medications due to intolerance or poor compliance provided they had a historical IOP of 21 mm Hg or higher. Exclusion

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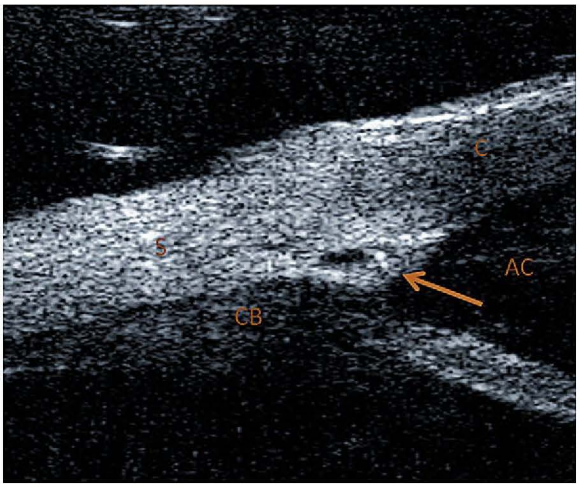

Figure 1. A UBM image of the anterior angle captured at the conclusion of the canaloplasty procedure. The arrow points to the 2 suture knots located in the anterior aspect of the viscodilated Schlemm canal (AC = anterior chamber; C = cornea; CB = ciliary body; I = iris; S = sclera).

criteria included neovascular disease, uveitis, peripheral anterior synechiae, angle recession, developmental or secondary glaucoma with the exception of pigmentary and exfoliative glaucoma, and patients with more than 2 laser trabeculoplasty procedures. Only 1 eye per patient was eligible.

Surgical Technique

A detailed description of the surgical procedure was published in the 1-year interim clinical report.[12] After a nonpenetrating 2-flap dissection technique to expose Schlemm canal, a flexible microcatheter (iTrack 250A, iScience Interventional Corp.) was used to dilate the full circumference of the canal by injecting sodium hyaluronate 1.4% (Healon GV) during catheterization. The microcatheter has a 200 µm diameter shaft with an atraumatic distal tip approximately 250 µm in diameter, a lumen through which the ophthalmic viscosurgical device is delivered, and an illuminated tip so the surgeon can guide the microcatheter by observing the beacon tip transsclerally. A Descemetic window was formed just before or immediately after catheterization of the canal. After circumferential catheterization, a 10-0 polypropylene (Prolene) suture was tied to the microcatheter tip and the device was withdrawn, pulling the suture into the canal. The suture was cut from the microcatheter and then tied in a loop encircling the inner wall of the canal. The suture loop was tightened to distend the trabecular meshwork inward, placing the tissues in tension, and then locking knots were added. The deep flap was excised and the superficial flap sutured watertight to prevent bleb formation.

Statistical Analysis

The efficacy analysis was stratified by the treatment received, and the results of different subgroups of patients were evaluated. Group 1 included all patients meeting the inclusion and exclusion criteria, Group 2 included all patients with successful suture implantation during canaloplasty alone, and Group 3 included all patients with successful suture implantation during canaloplasty combined with cataract surgery. The primary endpoints included mean IOP and mean number of glaucoma medications at each follow-up visit. Combination glaucoma medications were enumerated as individual medications in this study. The secondary endpoints included surgical and postsurgical complications and secondary interventions.

Baseline characteristics between surgical groups were compared using the Pearson chi-square test for categorical variables, such as sex, race, right and left eyes, previous surgery, and diagnosis and analysis of variance (ANOVA) for IOP, visual acuity (logMAR units), and number of glaucoma medications.[14] In each of the 3 groups, repeated-measures ANOVA using a mixed-model approach for longitudinal data was applied to assess changes from baseline in IOP, acuity, and medications with Bonferroni adjusted *P* values for assessing group differences.[15] When comparing Group 2 and Group 3, age, baseline IOP, and medications were included as covariates to control for possible confounding with the group-by-time interaction. The *F*-test for comparing slopes between groups from baseline through 36 months and differences in IOP, medications, and visual acuity was performed at specific time points. A compound symmetry covariance structure was used to handle the repeated measurements for the same patients at different time points. Two-tailed values of *P* less than or equal to 0.05 were considered statistically significant with adjustment for multiple comparisons as appropriate. The SPSS statistical package (version 18.0, SPSS Inc./IBM) was used for analysis of the data.

RESULTS

Demographics

The study cohort consisted of patients who met inclusion and exclusion criteria, provided consent for long-term follow-up, and completed baseline visits. Group 1 (all included patients) consisted of 157 eyes of 157 patients at baseline, with 134 eyes (84.7%) completing the 36-month visit. Of the remaining 23 patients, 9 (5.7%) were lost to follow-up, 7 (4.5%) had additional glaucoma surgery, 3 (1.9%) were terminated due to study site closure, 3 withdrew from the study for personal reasons, and 1 (0.6%) died after 24 months from reasons not related to the study.

Table 1 shows the patients' demographics. Patients were predominantly white and female, with the majority of the cohort diagnosed with POAG. Twenty-five eyes (15.9%) were pseudophakic at baseline. The successful placement of a tensioning suture into Schlemm canal was achieved in 133 eyes (84.7%). The primary reason successful suture placement was not achieved was surgery related, such as the microcatheter tip entering a collector channel ostium, deviating from the intended 360-degree circular Schlemm canal. However, no significant adverse events were recorded as a result of the failure to fully catheterize the canal. Eyes that were not completely catheterized to allow placement of a tensioning suture

Table 1. Study group demographics.

Parameter	Value
Patients/eyes, n	157
Age in years	
Mean ± SD	67.6 ± 11.6
Range	37.4 to 88.4
Sex, n (%)	
Female	84 (53.5)
Male	73 (46.5)
Race, n (%)	
White	144 (91.7)
Black	8 (5.1)
Hispanic	4 (2.5)
Asian	1 (0.6)
Glaucoma diagnosis, n (%)	
Primary open angle glaucoma	140 (89.2)
Pseudoexfoliative glaucoma	11 (7.0)
Mixed mechanism	3 (1.9)
Pigmentary dispersion glaucoma	3 (1.9)
Previous ocular surgery, n (%)	
Cataract	25 (15.9)
Laser trabeculoplasty	24 (15.3)
Viscocanalostomy	12 (7.6)
Laser peripheral iridotomy	9 (5.7)
Nd:YAG capsulotomy	2 (1.3)
Cyclophotocoagulation	1 (0.6)

n = sample size
Nd:YAG = neodymium YAG

were viscodilated to the extent possible by catheterizing the canal from both ostia. One hundred twenty-one eyes (77.1%) had canaloplasty only with or without tensioning suture placement, and 36 eyes (22.9%) with visually significant cataract had canaloplasty with or without suture placement combined with cataract extraction (phacocanaloplasty).

Change in Intraocular Pressure and Antiglaucoma Medication Use

Table 2 and Figure 2 show the efficacy results by group. In Group 1 (all included eyes), the decrease in IOP from baseline to 36 months was 36.1%. Twelve (7.6%) of 157 eyes were on no antiglaucoma medications and 33 eyes (21.0%) were on 3 or more antiglaucoma medications at baseline compared with 66 of 134 eyes (49.3%) and 4 eyes (3.0%), respectively, at 36 months. The IOP and medication use were significantly decreased from baseline at all time points ($P < .001$).

In Group 2 (canaloplasty alone with successful suture implantation), the decrease in IOP from baseline to 36 months was 34.0%. Four (3.9%) of 103 eyes were on no antiglaucoma medications and 21 eyes (20.4%) were on 3 or more medications at baseline compared with 37 (41.6%) of 89 eyes and 4 eyes (4.5%), respectively, at 36 months. The IOP and medication use were significantly decreased from baseline at all time points ($P < .001$). In 18 eyes that had canaloplasty alone, a tensioning suture was not placed because Schlemm canal could not be completely catheterized. This subgroup had a mean baseline IOP of 25.2 ± 6.4 mm Hg and a mean medication use of 2.1 ± 1.0 medications per eye, decreasing to 16.2 ± 3.3 mm Hg on 1.1 ± 0.8 medications, respectively, at 36 months. The reduction in IOP from baseline to 36 months was 35.7%. The sample size in this subgroup was too small for a meaningful statistical comparison with Group 2.

In Group 3 (canaloplasty with successful suture placement combined with phacoemulsification), the decrease in IOP from baseline to 36 months was 42.1%. The IOP and medication use were significantly decreased from baseline at all time points ($P < .001$). Baseline IOP was not significantly different between

Table 2. Outcomes.

	Group 1: All Eyes			Group 2: Canaloplasty Alone with Suture Placement			Group 3: Phacocanaloplasty with Suture Placement		
Exam	n	Mean IOP (mm Hg) ± SD	Mean Meds (n) ± SD	n	Mean IOP (mm Hg) ± SD	Mean Meds (n) ± SD	n	Mean IOP (mm Hg) ± SD	Mean Meds (n) ± SD
Baseline	157	23.8 ± 5.0	1.8 ± 0.9	103	23.5 ± 4.5	1.9 ± 0.8	30	23.5 ± 5.2	1.5 ± 1.0
Postop(mo)									
3	136	15.7 ± 4.2	0.3 ± 0.6	91	15.9 ± 3.8	0.3 ± 0.7	25	14.0 ± 3.9	0.1 ± 0.3
6	132	15.4 ± 3.7	0.3 ± 0.6	86	16.1 ± 3.4	0.4 ± 0.7	25	12.8 ± 2.9	0.1 ± 0.3
12	136	15.6 ± 4.2	0.5 ± 0.8	91	16.1 ± 3.9	0.6 ± 0.8	27	13.6 ± 4.1	0.1 ± 0.4
18	128	15.9 ± 4.1	0.5 ± 0.8	87	16.2 ± 4.1	0.6 ± 0.8	20	14.5 ± 3.6	0.2 ± 0.4
24	132	15.8 ± 4.2	0.6 ± 0.8	89	16.1 ± 4.0	0.6 ± 0.8	25	13.4 ± 3.2	0.2 ± 0.4
30	122	15.6 ± 4.2	0.6 ± 0.8	82	16.3 ± 4.5	0.8 ± 0.8	25	13.8 ± 3.2	0.2 ± 0.5
36	134	15.2 ± 3.5	0.8 ± 0.9	89	15.5 ± 3.5	0.9 ± 0.9	27	13.6 ± 3.6	0.3 ± 0.5

IOP = intraocular pressure; Meds = medications; n = sample size

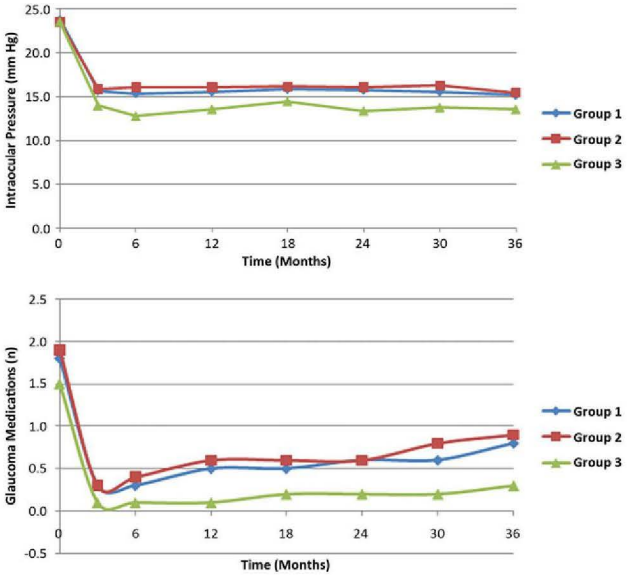

Figure 2. Graph comparing efficacy outcomes through 36 months in the 3 groups.

Group 2 and Group 3 ($P=.68$); however, postoperative IOP was lower in Group 3 at all time points ($P=.095$ at 36 months). Figure 3 shows a scatterplot graph of the baseline and 36-month postoperative IOP in all eyes in Group 2 and Group 3.

Visual Acuity

At 36 months, 13 (8.3%) of 157 eyes in Group 1 lost 2 or more lines (0.2 logMAR) of CDVA. The loss of visual acuity was attributed to glaucoma progression in 6 eyes (3.8%), cataract in 3 eyes (1.9%), age-related macular degeneration in 2 eyes (1.3%), and previously existing Fuchs' corneal dystrophy in 1 eye (0.6%); the reason for the visual acuity decrease in 1 eye was not reported. Group 2, which had a mean baseline CDVA of 0.22 ± 0.36 logMAR and a mean CDVA of 0.20 ± 0.25 logMAR at 36 months, had no significant change from baseline values ($P=1.00$).

Success

Table 3 shows the success results stratified by the absolute IOP readings in Group 2 and Group 3. Complete success was defined as reaching the specified IOP without antiglaucoma medication and a qualified success, as including the use of 1 or 2 medications. At 36 months, 36.0% of Group 2 eyes attained an IOP of 18 mm Hg or lower with no medications and 77.5% achieved a qualified success. In Group 3, 70.4% of eyes achieved an IOP of 18 mm Hg or lower with no medications and 88.9% achieved a qualified success. Table 3 also shows the success results stratified by absolute IOP readings and a 25% reduction in IOP from the maximum baseline IOP. Figure 4 shows

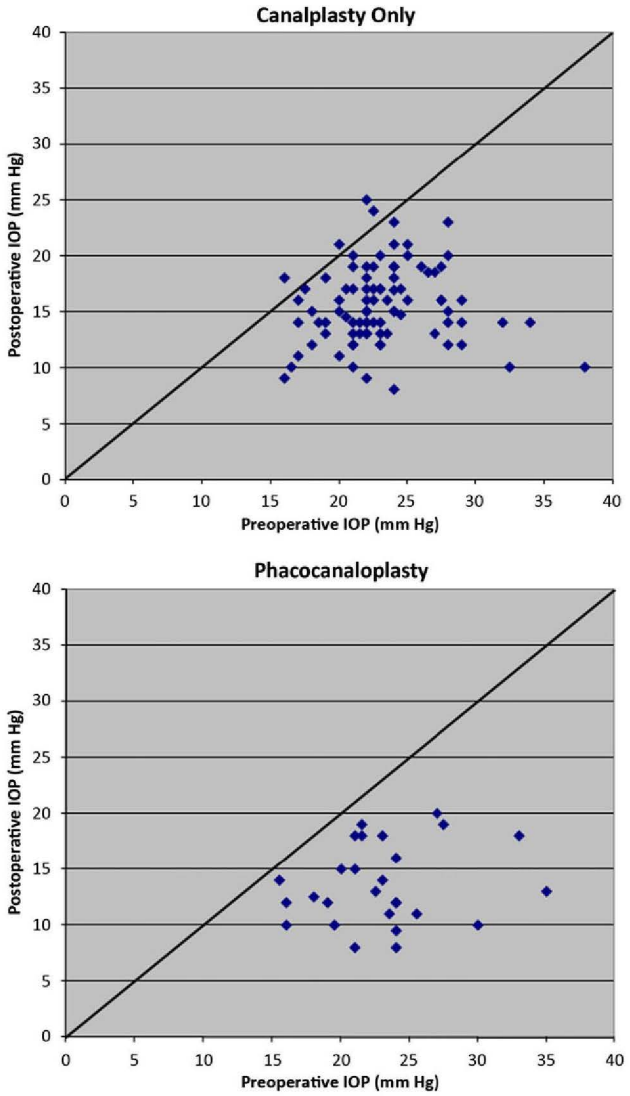

Figure 3. Scatterplot of preoperative IOP after 36 months in Group 2 (*top*) and Group 3 (*bottom*). Each point represents 1 eye. Points falling below the oblique line, which represents no change, are lower than the preoperative readings (IOP = intraocular pressure).

Kaplan-Meier survival plots for cumulative failure rates in Group 2 and Group 3 using the failure criterion of an IOP over 18 mm Hg on 2 consecutive visits. The chi-square approximations for log-rank and Wilcoxon tests comparing the failure proportions in Group 2 and Group 3 show a significant difference in the cumulative failure rate ($P<.03$).

Surgical and Postsurgical Complications

Overall, the frequency of surgical and postsurgical complications was low, with 16 adverse events in 12 eyes. Table 4 shows all ocular-related surgical and postoperative complications reported regardless of severity. Most complications occurred intraoperatively and in the early postoperative phase (≤90

Table 3. Success results at 12, 24, and 36 months in Group 2 and Group 3.

	Success Rate (%)					
	Group 2			Group 3		
	12 Months	24 Months	36 Months	12 Months	24 Months	36 Months
Complete success						
≤21 mm Hg	57.1	48.9	40.4	85.2	79.2	77.8
≤21 mm Hg and ≥25% IOP reduction*	50.5	42.7	34.8	81.5	76.0	70.4
≤18 mm Hg	48.4	40.9	36.0	77.8	75.0	70.4
≤18 mm Hg and ≥25% IOP reduction*	47.3	38.2	33.7	74.1	72.0	63.0
≤15 mm Hg	34.1	23.9	21.3	66.7	62.5	51.9
≤15 mm Hg and ≥25% IOP reduction*	34.1	23.6	21.3	66.7	60.0	51.9
Qualified success						
≤21 mm Hg	93.4	93.3	95.5	96.3	100.0	100.0
≤21 mm Hg and ≥25% IOP reduction*	79.1	80.9	85.4	88.9	100.0	92.6
≤18 mm Hg	70.3	74.2	77.5	85.2	92.0	88.9
≤18 mm Hg and ≥25% IOP reduction*	68.1	70.8	76.4	77.8	92.0	81.5
≤15 mm Hg	46.2	46.1	55.1	70.4	76.0	70.4
≤15 mm Hg and ≥25% IOP reduction*	46.2	46.1	55.1	70.4	76.0	70.4

IOP = intraocular pressure
*Reduction from maximum baseline IOP

days postoperatively). Intraoperative complications included partial suture extrusion through the trabecular meshwork, Descemet's detachment without involvement of the visual axis in 1 eye that resolved by 6 months postoperatively, and microhyphema, defined as circulating red blood cells without layered blood in the anterior chamber.

During the early postoperative period, the most common complications were microhyphema, hyphema, and elevated IOP (≥30 mm Hg). The hyphema resolved by the 1-week visit except in 3 eyes (1.9%), in which it resolved by 1 month postoperatively. The IOP rises were transient and resolved by the next scheduled follow-up except in 3 eyes (1.9%), 1 of which was treated with neodymium:YAG (Nd:YAG) goniopuncture for scarring of the trabeculo-Descemetic window and 2 of which were ultimately converted to trabeculectomies. All Descemet's membrane detachments had no visual axis involvement and resolved by the next scheduled visit except in 1 eye, in which the detachment resolved by 6 months postoperatively. The case of hypotony (IOP ≤5 mm Hg with shallow anterior chamber) was observed 1 day postoperatively and resolved by the next scheduled visit.

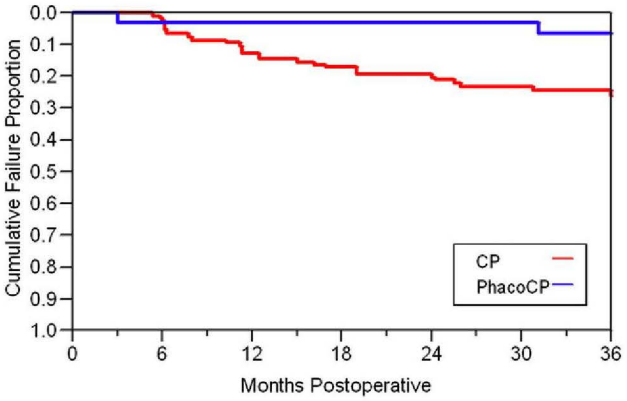

Figure 4. Kaplan-Meier plots of the cumulative probability of failure in Group 2 and Group 3. Failure was defined as an IOP higher than 18 mm Hg on 2 consecutive visits (CP = canaloplasty).

During the late postoperative period, the most common complications were cataract and elevated IOP (≥30 mm Hg). Three instances of elevated IOP in 2 eyes were successfully treated with glaucoma medical therapy. One eye with an IOP of 40 mm Hg at 869 days was believed to be a steroid responder after cataract surgery and was effectively treated with glaucoma medical therapy. An IOP rise of 30 mm Hg in 1 eye was attributed to a medication side effect and resolved after discontinuation of the drug. The remaining 5 eyes required further intervention or a combination of interventions including Nd:YAG goniopuncture, iridoplasty, cyclophotocoagulation, and trabeculectomy. In general, blebs were infrequent, and the 4 (2.5%) blebs reported were described as flat and diffuse.

Postoperative Interventions

Table 5 shows all interventions, defined as any procedure or process performed after surgery with

Table 4. Ocular-related surgical and postsurgical complications.

Complication	Number (%)
Surgical/early postoperative (≤90 days)	
Microhyphema (<1.0 mm layered blood)	19 (12.1)
Hyphema (≥1.0 mm layered blood)	16 (10.2)
Elevated intraocular pressure	10 (6.4)
Descemet's membrane detachment	5 (3.2)
Wound hemorrhage (corneal incision, conjunctiva, TDW)	4 (2.5)
Suture extrusion through trabecular meshwork	2 (1.3)
Hypotony (IOP ≤5 mm Hg with shallow anterior chamber)	1 (0.6)
Late postoperative (>90 days)	
Cataract	20 (12.7)
Elevated intraocular pressure	10 (6.4)
Blebs at 36 months	4 (2.5)
Suture extrusion through trabecular meshwork	1 (0.6)

TDW = trabeculo-Descemetic window

Table 5. Postoperative Interventions.

Type	Number (%)
Surgical	
Cataract surgery	20 (12.7)
Trabeculectomy	4 (2.5)
Canaloplasty	1 (0.6)
Laser	
Nd:YAG goniopuncture	14 (8.9)
Nd:YAG capsulotomy	12 (7.6)
Cyclophotocoagulation	3 (1.9)
Peripheral laser iridotomy	2 (1.3)
Iridoplasty	2 (1.3)
Synechialysis	2 (1.3)
Selective laser trabeculoplasty	1 (0.6)
Other	
Conjunctival suture replacement	8 (5.1)
Wound revision	1 (0.6)
Paracentesis	1 (0.6)
Pars plana steroid injection (for CRVO)	1 (0.6)

CRVO = central retinal vein occlusion; Nd:YAG = neodymium:YAG

the goal of enhancing the success of the surgical outcomes. The most commonly performed procedures included cataract extraction, Nd:YAG goniopuncture, Nd:YAG capsulotomy, and conjunctival suture replacement. Patients who received additional glaucoma surgery, including trabeculectomy, cyclophotocoagulation, and repeat canaloplasty, were censored from further analysis after the reoperations and were categorized as failures in the Kaplan-Meier curve and log-rank test.

DISCUSSION

When incisional glaucoma surgery is required, a trabeculectomy has traditionally been performed.[16] However, the quest for superior glaucoma surgical procedures has been motivated by the need to achieve long-term IOP control in the safest possible manner. The 3-year results reported here show sustained pressure lowering accompanied by a low incidence of late postoperative complications.

Although it is difficult to compare results in studies with different patient populations and study designs, canaloplasty efficacy results are comparable to published reports of trabeculectomy 3 years postoperatively. Comparative studies of trabeculectomy show a mean IOP in the range of 12.5 to 17.7 mm Hg after 3 years with mean medication use in the range of 0.34 to 0.93.[17–20] In the Tube Versus Trabeculectomy Study,[20] the authors point out that the hypotonous eyes that were categorized as failures due to persistent low IOP had the effect of reducing the reported mean IOP.

In the study reported here, early complications included a 12.1% incidence of microhyphema, a 0.6% incidence of hypotony, and no instances of flat/shallow anterior chambers or choroidal detachment. With canaloplasty, it is not uncommon to observe a small amount of blood in the anterior chamber, which likely occurs when the IOP decreases to less than the episcleral venous pressure. In comparison, the incidence of hyphema after trabeculectomy is reported to be in the range of 3% to 43%.[10,21–25] The incidence of hypotony as a postoperative complication of trabeculectomy is reported as between 10% and 42%.[21–25] Choroidal detachment subsequent to a trabeculectomy has been reported to range from 1% to 29%.[21,23,25]

Late complications after canaloplasty were infrequent. Only 4 (2.5%) blebs were observed at 36 months and there were no long-term bleb-related complications. In contrast, the late postoperative complications subsequent to trabeculectomy have been well described.[20] Bindlish et al.[26] report a 42.3% incidence of delayed hypotony occurring at a mean of 26.1 months subsequent to mitomycin-C (MMC)-augmented trabeculectomy. In addition, the authors report that bleb leak occurred in 18 eyes (14.6%) a mean of 27.9 months after trabeculectomy and that up to 8% of new cases of hypotony occurred 4 to 5 years postoperatively.

In the 3-year follow-up period in our canaloplasty study, 12.7% of patients had cataract progression that was potentially related to the procedure or age-related progression; 3.8% of these eyes had significant preexisting cataracts. For patients who did not have

significant preexisting cataract, the mean length of time to postoperative cataract extraction was 24.0 months. In comparison, a study of patients with a mean age of 43.7 years by Adelman et al.[27] reports a cataract extraction rate of 24% after initial trabeculectomy, with a mean time to postoperative cataract extraction of 26 months.

An indicator of surgical success could include the number of repeated surgical interventions required to maintain the target IOP. For the postoperative management of the Descemetic window and distended trabecular meshwork created during canaloplasty, secondary procedures were infrequent and included Nd:YAG goniopuncture, iridoplasty, and synechialysis. Because canaloplasty is not dependent on bleb formation, immediate postoperative care does not entail bleb massage or suture release to enhance flow. In comparison, Taube et al.[28] report that the mean number of visits to an ophthalmologist during the first postoperative year was 14.1 $\pm$ 3.1 per patient, with 93% of patients requiring bleb manipulations. King et al.[29] examined the type and frequency of postoperative bleb manipulations after trabeculectomy with intraoperative MMC and found that 93 (78.2%) of 119 trabeculectomies were followed by some form of bleb manipulation. Procedures requiring fewer follow-up visits and postoperative interventions could speak to a procedure being more cost effective with less resource utilization and greater convenience for the patient and surgeon.

The subset of eyes having primary cataract surgery in conjunction with canaloplasty surgery had a lower IOP than eyes having canaloplasty alone 3 years postoperatively, which suggests a combined beneficial effect. It may be surmised that removal of the natural lens improves outflow by further increasing trabecular meshwork tensioning in conjunction with canaloplasty. This potential advantage is supported by other studies of nonpenetrating glaucoma surgery in combination with phacoemulsification cataract surgery.[30–32] In contrast, some studies[33–36] found that phacotrabeculectomy was not as effective as trabeculectomy in reducing IOP.

The results in this multicenter prospective clinical trial provide further evidence that canaloplasty safely and effectively lowers IOP with persistent control of IOP through a 3-year postoperative period. The use of a flexible microcatheter to circumferentially viscodilate and suture tension Schlemm canal facilitates restoration of aqueous outflow in open-angle glaucoma. Canaloplasty did not demand the close postoperative management that is often required after trabeculectomy. Late postoperative complications were infrequent compared with the well-documented long-term risks associated with trabeculectomy.

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EXHIBIT 10

From: David DVanMeter@Ivantis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DVANMETER]
Sent: 6/14/2017 4:02:10 PM
To: Helene Spencer [hspencer@ivantisinc.com]; Ken Galt [kgalt@ivantisinc.com]; Brett Trauthen [btrauthen@ivantisinc.com]; Todd Abraham [tabraham@ivantisinc.com]; Brandon Lorry [blorry@ivantisinc.com]; Jennifer Wilson [jwilson@ivantisinc.com]
Subject: BOD Meeting Tone / Comments - Please read - Final Version
Attachments: 17 Jun BOD Ivantis June 14 Rev SMT Version.pptx

Importance: High

All:

Please see attached – modestly tweaked and "now final" version, so each of you should just make sure you look attached and below so as not to be caught by something you were not expecting.

This will be a great meeting, thanks all for the great work.

Several points:

[redacted]

[redacted]

That's it. Thanks all.

Dave Van Meter
President & CEO
Ivantis, Inc.
38 Discovery, Suite 150
Irvine, CA 92618
office 949 333 1311
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dvanmeter@ivantisinc.com
www.ivantisinc.com

EXHIBIT 11

[redacted]

From: Todd Abraham [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E64B4F61A56498CB8D6BF1CC7AF624A-TABRAHAM]
Sent: 6/28/2017 9:57:11 PM
To: David DVanMeter@Ivantis [dvanmeter@ivantisinc.com]
Subject: RE: Hydrus Delivery System Evaluation with [redacted]

[redacted]

Todd

Todd Abraham
VP Operations
tabraham@ivantisinc.com *Office: (949) 333-1335* *Cell: (949) 533-2410* *www.Ivantisinc.com*

From: Dave Van Meter
Sent: Wednesday, June 28, 2017 2:44 PM
To: Todd Abraham <TAbraham@ivantisinc.com>
Subject: FW: Hydrus Delivery System Evaluation with [redacted]

[redacted]

Dave Van Meter
President & CEO
Ivantis, Inc.
38 Discovery, Suite 150
Irvine, CA 92618
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dvanmeter@ivantisinc.com
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From: Ken Galt <KGalt@ivantisinc.com>
Date: Wednesday, June 28, 2017 at 2:37 PM
To: [redacted]Todd Abraham <TAbraham@ivantisinc.com>
Cc: Dave Van Meter <DVanMeter@ivantisinc.com>
Subject: RE: Hydrus Delivery System Evaluation with [redacted]

[redacted]

[redacted]

Best regards,
Ken

From: [redacted]
Sent: Wednesday, June 28, 2017 2:26 PM
To: Todd Abraham <TAbraham@ivantisinc.com>
Cc: Ken Galt <KGalt@ivantisinc.com>; Dave Van Meter <DVanMeter@ivantisinc.com>
Subject: Re: Hydrus Delivery System Evaluation with [redacted]

Todd and Ken!

[redacted]

This message and any included attachments are from [redacted] and are intended only for the addressee. The contents in this message contain confidential information belonging to the sender that is legally privileged. Unauthorized forwarding, printing, copying, distribution, or use of such information is strictly prohibited and may be unlawful. If you are not the addressee, please promptly delete this message and notify the sender of the delivery error by e-mail. This e-mail is informational only, not secure, and is not intended for patient communication. It is not intended for diagnosis and treatment of any health condition, nor is it a substitute for in-office, professional medical advice. The transmission of information from this email to you is not intended to create, nor does it create a physician-patient relationship between you and Dr. Sadri.

On Jun 28, 2017, at 2:18 PM, Todd Abraham <TAbraham@ivantisinc.com> wrote:

[redacted]

[redacted]

Kind Regards,

Todd

Todd Abraham
VP Operations
tabraham@ivantisinc.com *Office: (949) 333-1335* *Cell: (949) 533-2410* *www.Ivantisinc.com*

From: [redacted]
Sent: Wednesday, June 28, 2017 12:04 PM
To: Ken Galt <KGalt@ivantisinc.com>
Cc: Todd Abraham <TAbraham@ivantisinc.com>; Triet Tran <TTran@ivantisinc.com>; Jennifer Wilson <JWilson@ivantisinc.com>; Main Conference Room <CRoom@ivantisinc.com>
Subject: Re: Hydrus Delivery System Evaluation with [redacted]

[redacted]

On Jun 28, 2017, at 8:56 AM, Ken Galt <KGalt@ivantisinc.com> wrote:

[redacted]

Ken

[redacted]

[redacted] Looking forward to meeting you then.

Best regards,
Ken Galt, VP, R&D
<ATT25196 1.jpg>
Ivantis, Inc.
38 Discovery, Suite 150
Irvine, CA 92618
P 949.333.1312

[redacted]

EXHIBIT 12

[redacted]

From: David DVanMeter@Ivantis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DVANMETER]
Sent: 7/10/2017 11:27:12 PM
To: Todd Abraham [tabraham@ivantisinc.com]; Brandon Lorry [blorry@ivantisinc.com]
Subject: Re: Slider Physician Evaluation Notes - Update as of 7/8

Well, gents….

[redacted]

Thanks,

Dave

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Irvine, CA 92618
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From: Todd Abraham <TAbraham@ivantisinc.com>
Date: Monday, July 10, 2017 at 2:18 PM
To: Dave Van Meter <DVanMeter@ivantisinc.com>, Ken Galt <KGalt@ivantisinc.com>, Brandon Lorry <BLorry@ivantisinc.com>, Michael Chodzko <MChodzko@ivantisinc.com>, Helene Spencer <HSpencer@ivantisinc.com>
Subject: Slider Physician Evaluation Notes - Update as of 7/8

So far we have had 8 docs in…. Ken has all the formal questionnaire's from the protocol. Below are my additional notes from the 3 most recent sessions and attached are all my add'l notes for all 8 sessions. All have been pleasantly surprised in Hydrus ease of use.

Lot's of good feedback so far…. From a preference scoring perspective, nobody has been hell no for any of the designs. So far we are at

? Old Wheel: 2

? New Wheel: 2

? Slider: 4

For those who preferred a wheel:

? 3 of the 4 had very small hands.

? No strong opinions…. Could live with slider. Preference for Wheel predominantly feel…. No much detail provided.

? Unsolicited [redacted] reached out after his eval to comment that although he selected the wheel he thought more and felt it was because he had small hands and should have gripped differently with the slider to take advantage of the known travel etc.

For those preferring the Slider:

? These folks were pretty firm in their choice and could articulate why (comments on questionnaires) with the biggest advantage being knowing exactly where you are in deployment.

==========

[redacted]

? Describe doc / practice: Comprehensive Opthamologits, does ~10 surgeries/week. iStent user (50+ cases), no Zen, No Cypass

? Training deck: started 12:40pm ended: 1:20pm

○

? Comments/Dialogue prior to Eval:

○ Thoughts on MIGS? What MIGS do you use today?

○ If iStent:.

✍ ? What would it take you to switch from iStent?

? "I can't wait!"….. "iStent is hit or miss…. Seems like technology issues, visualization can be rough and my results really vary"….

? ?Would head to head data with a 30% or better advantage matter?

○ "Absolutely!"

✍ ? How do you know when you are in the right place with iStent?

? I have learned how to get it in the TM in the right place but don't know if it is in a collector channel

✍ ?What do you like about Glaukos?

? They opened the space and added to our Cataract Surgeon arsenal

? The training was “okay” but they have not followed up with any add’l training or best practices

✍ ?How should we market Hydrus? Other services?

? Provide tools with best practices, FAQs, example tough cases and how other docs handled them, etc.

✍ Do you see MIGs procedures transitioning to the office?

? I can certainly envision it.

o Hydrus comments during training deck

✍ Does not use miotic

✍ For OVD, uses Provisc, Healon and HEalon GV…. Glaukos did not speak to any preferred OVD in training

o

? Comments during hands on eval:

o Sequence: old wheel, new slider, new wheel

o #1 preference: Slider

o Comments:

✍ “Initially I felt the Slider was clunky but it worked and I liked it more as I used it.” “The wheel takes multiple movements of the finger and could cause device movement”.

✍ Overall

? “Easier than I thought”

? Tracks easily despite size”

? “Based upon my experience of 3 in the lab this is pretty good”

o Preference versus iStent:

✍ Hydrus (initial) overall ease of use: 4 confidence in placement: 5

✍ iStent (initial) 2 2

✍ iStent (experienced) 2 2

[redacted]

[redacted]

? Describe doc / practice: Comprehensive Opthomologist. Works for a huge group (over 30 centers... Retina Group / Acuity Eye). Most patients are HMO or Medi. She operates in 2 of their surgery centers and does ~8 surgeries per week. She went through the iStent training ~2 or 3 years ago but has not implanted in patients yet.... With their coverage Dr. Beckman says payors would not cover iStent. She has no Xen or Cypass experience.

o Note: Is this true regarding HMO/Medi coverage?

? Training deck: started 2:40pm ended 3:25pm

o

? Comments/Dialogue prior to Eval:

o Thoughts on MIGS? What MIGS do you use today?

✍ Very interested, wants to use them but covers with her patient population has been an obstacle.

o If iStent:.

✍ ? What would it take you to switch from iStent?

? NA

✍ ? How do you know when you are in the right place with iStent?

? NA

✍ ?What do you like about Glaukos?

? Training was “fine, not great”

✍ ?How should we market Hydrus? Other services?

✍ Do you see MIGs procedures transitioning to the office?

? Yes if you have a procedure room. Some Kaiser centers in NorCal are doing Cataracts in their office procedure room settings.

o Hydrus comments during training deck

o

? Comments during hands on eval:

o Sequence: Old wheel, new wheel, new slider

o #1 preference: Old Wheel (despite Slider comments below)

o Comments:

✍ On the new wheel: “I can feel the COGs a bit more but not very significant versus the other wheel”.

[redacted] IVANTIS_SS_00166429

- ✍ On the Slider: "I didn't mind it and I may like it even better…. I like knowing where I am".
- ✍ Overall on Hydrus: "I like that it is bigger and you know you have it in the right place".

- ○ Preference versus iStent:
- ○
- ✍ Hydrus (initial) overall ease of use: 4 confidence in placement: 4
- ✍ iStent (initial) 3 2.5
- ✍ iStent (experienced) = N/A

[redacted]

? Describe doc / practice: ~15 surgeries/week. Self-described "early adopter" . iStent user…. Started w/ iStent, switched to Trabectome and became a "trainer". After 30+ cases with Trabectome became disenchanted and switched back to iStent because it is "cleaner and easier…. Looks better the next day etc" All in has done > 35 iStents.

? Training deck: started 8:50am ended 9:35am

? Comments/Dialogue prior to Eval:

- ○
- ○ iStent:.
- ✍ ? What would it take you to switch from iStent?

? Show me studies/date & get me familiar. If it is better I am happy to switch.

✍ ? How do you know when you are in the right place with iStent?

? Visual, feel…. See blush. "I pull it to tent the TM…. I clear blood to see…. Tap it in". "I have no confidence I am in a collector channel".

✍ ?Your iStent results?

? Seems to be working…. I stop all drops after surgery and see where patients are before re-starting any drops. So far about 40% of my iStent patients do need to be put back on at least 1 med.

✍ ?What do you like about Glaukos?

? Good training, sharp people…. They put a line on my scope to ease my adjustment etc…

✍ ?How should we market Hydrus? Other services?

? Better product and better efficacy

? Continuing education, updates on tips & tricks, physician forums to discuss methods/results

✍ Do you see MIGs procedures transitioning to the office?

? Yes, I can't see why not

○ Hydrus comments during training deck

✍ Does not use miotic

✍ Does use Healon GV

✍ "Hydrus looks more intuitive"

○

? Comments during hands on eval:

○ Sequence: old wheel, new slider, new wheel

○ #1 preference: Torn between old wheel and new slider…. Could go either way but is forced to choose he picks old wheel.

○ Preference versus iStent:

○

✍	Hydrus (today)	overall ease of use: 5	confidence in placement: 5
✍	iStent (initial)	3	3
✍	iStent (experienced)	4	4

Todd

Todd Abraham
VP Operations
Ivantis, Inc.
38 Discovery, Suite 150, Irvine, CA 92618
tabraham@ivantisinc.com Office (949) 333-1335 Cell: (949) 533-2410
www.ivantisinc.com

[redacted]

EXHIBIT 13

[redacted]

From: Syed, Sahil [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AF6F37D488E843BEBB25205E41F08B35-SYEDSA6]
Sent: 6/24/2022 8:10:08 PM
To: dach, materialmaster (Gen) [materialmaster.dach@alcon.com]; Szymczak, Jerzy(EXT) [jerzy.szymczak@alcon.com]; Kopp, Patric [patric.kopp@alcon.com]; Abraham, Todd [todd.abraham@alcon.com]; Koch, Kévin [kevin.koch@alcon.com]
CC: Thomas, Mark-Peter [mark-peter.thomas@alcon.com]; Singh, Shailender [shailender.singh@alcon.com]; Kreitner, Raphael [raphael.kreitner@alcon.com]; Da Costa, Cristina [cristina.da_costa@alcon.com]
Subject: RE: Ivantis - Switzerland extension for 100300294 (Hydrus)

Thanks team for the collaboration to get things set up here

Pricing is being worked on in separate workstreams so that information will follow in the coming weeks

Kind Regards

Sahil

Sahil Syed
Commercial Director, Europe | Surgical Glaucoma
Alcon Management, S.A.
Chemin de Blandonnet 8
1214 Vernier
Geneva
Switzerland

email: sahil.syed@alcon.com
Mobile: 07818 582 790
Mobile dial from outside UK: +44 7818 582 790

From: dach, materialmaster (Gen) <materialmaster.dach@alcon.com>
Sent: 24 June 2022 09:28
To: Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>; Kopp, Patric <patric.kopp@Alcon.com>
Cc: Syed, Sahil <sahil.syed@alcon.com>; Thomas, Mark-Peter <mark-peter.thomas@Alcon.com>; Singh, Shailender <Shailender.Singh@alcon.com>; Kreitner, Raphael <Raphael.Kreitner@alcon.com>; Da Costa, Cristina <cristina.da_costa@Alcon.com>
Subject: RE: Ivantis - Switzerland extension for 100300294 (Hydrus)

Hello Jerzy,

Yes, the same should be submitted for CH area. With the LDM ticket we can start the extension to Swiss Sales org. and plant. With the details provided in the email, that should be enough for the extension and PIR setup.

Additionally after the extension is done, we would need the ASP value, in this case in CHF currency, so that we can request supply price and then proceed with costing.

Damian Michalski
Local Data Steward, Commercial ERP Material Master – EMEA

Alcon Polska Sp. z o.o.
Marynarska 15, 02-674 Warszawa
M +48 669 210 655
damian.michalski@alcon.com
DACH, materialmaster materialmaster.dach@alcon.com

Alcon

From: Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>
Sent: Friday, 24 June 2022 09:54
To: Kopp, Patric <patric.kopp@Alcon.com>; dach, materialmaster (Gen) <materialmaster.dach@alcon.com>
Cc: Syed, Sahil <sahil.syed@alcon.com>; Thomas, Mark-Peter <mark-peter.thomas@Alcon.com>; Singh, Shailender <Shailender.Singh@alcon.com>; Kreitner, Raphael <Raphael.Kreitner@alcon.com>; Da Costa, Cristina <cristina.da_costa@Alcon.com>
Subject: Ivantis - Switzerland extension for 100300294 (Hydrus)

Patric and Damian : in connection with introduction of Ivantis Hydrus microstent on Swiss market prepared now by Sahil Syed and Raphael Kreitner in the field (cc)

Can you engage process as followed earlier for Germany

(i.e. local S&OP needs create a ticket in LDM for material extension as normal and LDS picks it up) ?

Damian, flow details below from Cristina da Costa, if questions at your disposal

Thank you Gentlemen and cc'ing Cristina for coordination

George (Jerzy)

[redacted]

Regards,
Jerzy (George) Szymczak
PMO Support for Customer Ops INTL

Alcon Global Services (AGS)
Marynarska 15, 02-674 Warsaw, Poland
M +48 605 099 269
Jerzy.Szymczak@alcon.com

From: Kopp, Patric <patric.kopp@Alcon.com>
Sent: Tuesday, May 24, 2022 1:55 PM
To: dach, materialmaster (Gen) <materialmaster.dach@alcon.com>
Cc: Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>; Syed, Sahil <sahil.syed@alcon.com>; Thomas, Mark-Peter <mark-peter.thomas@Alcon.com>; Singh, Shailender <Shailender.Singh@alcon.com>
Subject: RE: Ivantis - Germany transfer price request for EU SKU HYDRUS MICROSTENT CE Material Number – 100300294, Global Code F00018

Hi Damian,

have created a Ticket, as we don´t have anyone in DE who is responsible before Raphael Kreitner will join in June. Not sure if all is correct – let´s connect if something is missing

#13014

KR
Patric

Manager S&OP DACH - Surgical

Alcon Deutschland GmbH
Heinrich-von-Stephan-Straße 17
79100 Freiburg

Mobile +49 151 23890910
Patric.kopp@alcon.com

From: dach, materialmaster (Gen) <materialmaster.dach@alcon.com>
Sent: Montag, 23. Mai 2022 13:27
To: Singh, Shailender <Shailender.Singh@alcon.com>; Thomas, Mark-Peter <mark-peter.thomas@Alcon.com>; Kopp, Patric <patric.kopp@Alcon.com>
Cc: Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>
Subject: RE: Ivantis - Germany transfer price request for EU SKU HYDRUS MICROSTENT CE Material Number – 100300294, Global Code F00018

Hello,

[redacted].

[redacted]

[redacted]

Kind Regards,
Damian Michalski

From: Materialmaster,UK(Gen) <materialmaster.uk@alcon.com>
Sent: Tuesday, 17 May 2022 10:24
To: dach, materialmaster (Gen) <materialmaster.dach@alcon.com>; Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>
Subject: FW: Ivantis - Germany transfer price request for EU SKU HYDRUS MICROSTENT CE Material Number – 100300294, Global Code F00018

Hey Jerzy,

Damian is responsible for DACH.

Maria Chmielewska
Local Data Steward, UK & Nordics

Alcon Polska Sp. z o.o.
Marynarska 15, 02-674 Warszawa
M: +48 725 231 056
Maria.chmielewska@alcon.com
UK: materialmaster.uk@Alcon.com
Nordics: materialmaster.nordics@Alcon.com

Alcon

[redacted]

Sąd Rejonowy dla m.st. Warszawy, XIII Wydział Gospodarczy Krajowego Rejestru Sądowego,
KRS: 0000060964, NIP: 527-10-93-105, kapitał zakładowy 750.000 zł

From: Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>
Sent: Monday, May 16, 2022 4:52 PM
To: Chmielewska, Maria <Maria.Chmielewska@alcon.com>
Subject: Ivantis - Germany transfer price request for EU SKU HYDRUS MICROSTENT CE Material Number – 100300294, Global Code F00018

Maria: if you know who the contact for Germany is – can you pass it to the person (APL told me you know:) ?

Same logic as below with following codes

Germany

- [redacted]

From: Szymczak, Jerzy(EXT)
Sent: Monday, May 16, 2022 4:48 PM
To: Merrell-Jones, Tony <tony.merrell-jones@Alcon.com>
Cc: Chmielewska, Maria <Maria.Chmielewska@alcon.com>
Subject: Ivantis - UK transfer price request for EU SKU HYDRUS MICROSTENT CE Material Number – 100300294, Global Code F00018

Hi Tony, can you request the transfer price for Ivantis Hydrus using the transfer price tool ?

Context: am working on Ivantis integration from Customer Ops side, Maria will need it for UK Material Master as LDS, below email from Global IT request such procedure

In case of questions you can contact me on Teams video until 5pm UK time or on Wed

Thank you for your help,

George

= = =

[redacted]

[redacted]

SKU setup: plants and vendors for each

UK

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

Attached details sent to LDS on slides

Regards,
Jerzy (George) Szymczak
PMO Support for Customer Ops INTL

Alcon Global Services (AGS)
Marynarska 15, 02-674 Warsaw, Poland
M +48 605 099 269
Jerzy.Szymczak@alcon.com

[redacted]

From: Kurian, Manu <manu.kurian@Alcon.com>
Sent: Friday, May 13, 2022 8:48 PM
To: Verduch Arosa, Clara <clara.verduch_arosa@Alcon.com>; Pandey, Sudeep <sudeep.pandey@Alcon.com>; Chong, Melisa Li Yi <Melisa.Chong@Alcon.com>; Szymczak, Jerzy(EXT) <Jerzy.Szymczak@alcon.com>; Macivor, Angela <angela.macivor@Alcon.com>
Cc: St. John, Lawrence <lawrence.stjohn@Alcon.com>; Gerasimou, Kelli <Kelli.Gerasimou@alcon.com>; Ramirez, David <David.Ramirez@alcon.com>; Nandela, Joshua Paul <joshua_paul.nandela@Alcon.com>; Nunez, Jesus(EXT) <JesusFNunez.Tello@alcon.com>
Subject: Transfer price request

Hi everybody,

The transfer prices which we currently have are Ivantis transfer price. The desire is to re-calculate the transfer prices based on Alcon's methodology so could you request each site to request their transfer price through the transfer price tool?

I have also copied David Ramirez who may be able to help if you need info on the average selling price which Ivantis currently has, though I guess you may have separately calculated the expected ASP.

Best regards,

Manu Kurian
FRA Implementation Lead

6201 South Freeway
Fort Worth, TX 76134-2099, United States
T +1 817 568 6208 | M +1 404 993 1254
manu.kurian@alcon.com

Alcon

EXHIBIT 14

[redacted]

From: Andrew Basilio [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32FCE672473F480B8F3CE7F8F4C2D0BE-ABASILIO]
Sent: 3/24/2021 7:03:58 PM
To: Michael Chodzko [mchodzko@ivantisinc.com]; David Kimball [dkimball@ivantisinc.com]
CC: Todd Abraham [tabraham@ivantisinc.com]; Andy Schieber [andy@ingenarious.com]
Subject: RE: Equipment to support outflow study

Hi Mike,

I'll have the engineers check the lab to see if we still have this equipment. Do you know where you got this procedure from?

Thank you,

Andrew Basilio
Manager, Manufacturing & Facilities Engineering

IVANTIS

Ivantis Inc.,
201 Technology Dr.,
Irvine, CA 92618
O: 949-333-1351
C: 951-764-3917
abasilio@ivantisinc.com

From: Michael Chodzko <mchodzko@ivantisinc.com>
Sent: Wednesday, March 24, 2021 12:00 PM
To: Andrew Basilio <ABasilio@ivantisinc.com>; David Kimball <dkimball@ivantisinc.com>
Cc: Todd Abraham <tabraham@ivantisinc.com>; Andy Schieber <andy@ingenarious.com>
Subject: Equipment to support outflow study

David and Andrew, I hope you both are doing well. We are looking to conduct some outflow testing on a couple of Hydrus/ competitive devices using a perfusion model that believe we have at our facility somewhere. We have conducted these tests before but was many years ago and before my time as well as Todd's. I've copied Andy who ran the tests for us previously years ago. Andy said that we do/ did have the equipment available to run these tests at our facility. I have attached an older SOP for the perfusion testing that highlights the equipment we used to conduct the test.

Have either of you seen this equipment and/ or know if we have onsite? Thanks very much for your feedback.

Mike Chodzko
Vice President, Marketing & International Sales

Ivantis, Inc.
Office: 949 333-1314
Mobile: 949 300-6024
mchodzko@ivantisinc.com
www.ivantisinc.com

[redacted]

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS
URBANA DIVISION

FRENCHPORTE, LLC, FRENCHPORTE IP, LLC, Plaintiffs, v. C.H.I. OVERHEAD DOORS, INC., Defendant.	Case No. 2:21-cv-02014-CSB-EIL

JOINT MOTION RE [PROPOSED] ORDER GOVERNING DISCOVERY OF ELECTRONICALLY STORED INFORMATION

Plaintiffs Frenchporte, LLC and Frenchporte IP, LLC ("Frenchporte") and Defendant C.H.I. Overhead Doors, LLC ("C.H.I."), by and through their undersigned counsel, jointly move the Court to enter the attached [Proposed] Order Governing Discovery of Electronically Stored Information. On February 23, 2021, the Court adopted the schedule in the parties' Rule 26(f) Discovery Plan, which set a filing date of a proposed ESI protocol for March 11, 2021. (2/23/2021 Text Order.) The parties requested a brief extension of the deadline to submit a proposed ESI protocol to March 19, 2021 (Dkt. 25), which the Court granted. (3/12/2021 Text Order.) The parties have since conferred and reached agreement regarding a proposed ESI protocol and respectfully request that the Court enter the parties' attached proposed ESI protocol.

* * * *

Dated: March 19, 2021

Respectfully submitted,

/s/ *Geoffrey Mason* (with consent)
Geoffrey Mason
MOARBES LLP
2200 Pennsylvania Ave NW
Fourth Floor East
Washington, DC 20878
Tel.: (240) 888-7644
geoff.mason@moarbes.com

Attorney for Plaintiff FrenchPorte

/s/ *Gianni Cutri*
Gianni Cutri
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Tel.: (312) 862-2000
Fax: (312) 862-2200
gcutri@kirkland.com

Attorney for Defendant C.H.I. Overhead Doors, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on March 19, 2021, the foregoing document was filed electronically through the Court's Electronic Case Filing System. Service of this document is being made upon all counsel of record in this case by the Notice of Electronic Filing issued through the Court's Electronic Case Filing System on this date.

By: /s/ *Gianni Cutri*

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS

FRENCHPORTE, LLC, FRENCHPORTE IP, LLC, Plaintiffs, v. C.H.I. OVERHEAD DOORS, INC., Defendant.	Case No. 2:21-cv-02014-CSB-EIL

[JOINT PROPOSED] ORDER GOVERNING DISCOVERY OF ELECTRONICALLY STORED INFORMATION

The Court ORDERS as follows:

1. This Order supplements all other discovery rules and orders. It streamlines Electronically Stored Information ("ESI") production to promote a "just, speedy, and inexpensive determination" of this action, as required by Federal Rule of Civil Procedure 1.

2. This Order may be modified for good cause. If the parties cannot resolve their disagreements regarding modifications, the parties may submit their competing proposals and a summary of their dispute. Proposed modifications or disputes regarding ESI that counsel for the parties are unable to resolve will be presented to the Court at the initial case management conference, Fed. R. Civ. P. Rule 16(b) Scheduling Conference, or as soon as possible thereafter.

3. Costs will be shifted for disproportionate ESI production requests pursuant to Federal Rule of Civil Procedure 26. Likewise, a party's nonresponsive or dilatory discovery tactics will be cost-shifting considerations.

4. A party's meaningful compliance with this Order and efforts to promote efficiency and reduce costs will be considered in cost-shifting determinations.

5. Material produced in response to general ESI production requests under Federal Rules of Civil Procedure 34 and 45 shall be produced with the metadata fields, to the extent the metadata exists, and consistent with the requirements set forth in Appendix 1.

6. These data sources are not reasonably accessible because of undue burden or cost pursuant to Fed. R. Civ. P. 26(b)(2)(B) and ESI from these sources will not be searched, reviewed, or produced absent a showing of good cause:

a. backup systems and/or tapes, such as those used for disaster recovery;

b. systems, server, and network logs;

c. raw or voluminous partner, customer or driver data that expires or is overwritten on a set schedule, or driver or customer data subject to privacy restrictions or regulations;

d. systems no longer in use that cannot be accessed;

e. voice messages and other audio recordings;

f. instant messaging and chat application data;

g. text messages;

h. information from handsets, mobile devices, personal digital assistants, and tablets that is duplicative of information that resides in a reasonably accessible data source;

i. automatically saved versions of documents and emails;

j. deleted, slack, fragmented, or other data accessible only by forensics;

k. random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system;

l. on-line access data such as temporary internet files, history, cache, cookies, and the like;

m. dynamic fields of databased or log files that are not retained in the usual course of business; and

n. data in metadata fields that are frequently updated automatically, such as last opened dates.

7. Except as provided for in this paragraph, general ESI production requests under Federal Rules of Civil Procedure 34 and 45 must not include email or other forms of electronic correspondence (collectively "email"). To obtain email parties must propound specific email production requests utilizing the procedures set forth in paragraphs 8-11 (hereinafter "Specific Email Requests") except that general ESI production requests may be utilized to request production of plaintiff's emails that pertain to topics set forth in the complaint, emails related to prosecution of the Asserted Patent, emails related to any licensing negotiations or agreements regarding the Asserted Patent, and emails exchanged with non-parties to this suit regarding the Asserted Patent or the subject matter of the complaint.

8. Specific Email Requests will identify the custodian, search terms, and time frame. The parties will cooperate to identify the proper custodians, proper search terms and proper time frames.

9. Each requesting party must limit its Specific Email Requests to a total of five (5) custodians per producing party for all such requests. The parties may jointly agree to modify this limit without the Court's leave. The Court will consider contested requests for additional custodians per producing party, upon showing of good cause and distinct need based on the size, complexity, and issues of this specific case. Should a party serve Specific Email Requests for additional custodians beyond the limits agreed to by the parties or granted by the Court pursuant to this paragraph, the requesting party shall bear all reasonable costs caused by such additional discovery.

10. Each requesting party will limit its Specific Email Requests to a total of five (5) search terms per custodian per party. The parties may jointly agree to modify this limit without the Court's leave. The Court will consider contested requests for additional search terms per custodian, upon showing a distinct need based on the size, complexity, and issues of this specific case. The search terms must be narrowly tailored to particular issues. An email that hits on a search term is not presumptively relevant to a claim or defense or responsive to a discovery request. In the event a search term hits on more than 500 unique emails of a custodian, the parties will meet

and confer in good faith to determine whether the search parameters can be narrowed and still meet the needs of the case. A conjunctive combination of multiple words or phrases (e.g., "computer" and "system") narrows the search and will count as a single search term. A disjunctive combination of multiple words or phrases (e.g., "computer" or "system") broadens the search, and thus each word or phrase will count as a separate search term unless they are variants of the same word. Use of narrowing search criteria (e.g., "and," "but not," "w/x") is encouraged to limit the production and must be considered when determining whether to shift costs for disproportionate discovery. Should a party serve email production requests with search terms beyond the limits agreed to by the parties or granted by the Court pursuant to this paragraph, the requesting party shall bear all reasonable costs caused by such additional discovery.

11. Each party will use its best efforts to filter out common system files and application executable files by using a commercially reasonable hash identification process. Hash values that may be filtered out during this process are located in the National Software Reference Library ("NSRL") NIST hash set list. Additional culling of file types based on file header information may include, but are not limited to: Application Package File, Backup Files, Batch Files, Binary Disc Image, C++ File Formats, Cascading Style Sheet, Configuration File, Database File, Dictionary Files, Dynamic Link Library, Event Log Files, Executable Files, Hypertext Cascading Stylesheet, Java Archive Files, JavaScript files, JavaScript Source Code and Class Files, Macintosh Resource Fork Files, Package Manager Files, Program Files, Program Installers, Python Script Files, Shell Script Files, System or Temporary Files, Thumbnail Cache Files, Troff Files, TrueType Font Files, Windows Cabinet File, Windows Command Files, Windows File Shortcut, Windows Help Files, Windows Metafiles and Enhanced Metafiles, Windows Spool Files, Windows System File.

12. A party is required to produce only a single copy of a responsive document, and a party may de-duplicate responsive ESI across Custodians, as long as the metadata reflects all custodians in possession of that document. A party may also de-duplicate email threads and attachments as follows: In an email thread, only the most evolved responsive email in a thread will

be produced. Where an earlier-in-thread email has a responsive attachment not contained within the most evolved responsive email, the most evolved earlier-in-thread email containing the attachment will also be produced along with its attachment.

13. The parties agree to produce documents in the formats described in Appendix 1 to this Order. If particular documents warrant a different format, the parties will cooperate to arrange for the mutually acceptable production of such documents. The parties agree not to degrade the searchability of documents as part of the document production process.

14. The receiving party must not use ESI that the producing party asserts is attorney-client privileged or work product protected to challenge the privilege or protection.

15. Pursuant to Federal Rule of Evidence 502(d), the production of a privileged or work product protected ESI, whether inadvertent or otherwise, is not a waiver in the pending case or in any other federal or state proceeding.

16. The mere production of ESI in a litigation, including as part of a mass production, will not itself constitute a waiver for any purpose.

17. No provision of this Order affects the inspection or production of source code which will be collected and made available consistent with the Protective Order governing this case. To the extent source code files are contained within emails, as attachments to emails, or embedded within other ESI produced in accordance with this order, a slip sheet shall be provided to note where source code files have not been produced. Documents where source code has been redacted, however, need only include labels to note that source code has been redacted.

IT IS SO ORDERED this _____ day of _____, _____.

_____
United States Magistrate Judge

APPENDIX 1

PRODUCTION FORMAT AND METADATA

1. **Production Components.** Productions shall include, single page TIIFFs, Text Files, an ASCII delimited metadata file (.txt, .dat, or .csv) and an image load file that can be loaded into commercially acceptable production software (e.g., Relativity).

2. **Image Load File**. Image load file shall contain the following comma-delimited fields: BEGBATES, VOLUME, IMAGE FILE PATH, DOCUMENT BREAK, PAGE COUNT.

a. **Metadata Fields and Metadata File.** Each of the metadata and coding fields set for below that can be extracted shall be produced for each document.

Field Name	Field Description
AUTHLAST	Author(s) of native file
BCC	All recipients that were included on the "BCC" line of the email
BEGBATES	Beginning Bates number as stamped on the production image
BEGATTACH	First production Bates number of the first document in a family
CC	All recipients that were included on the "CC" line of the email
CUSTODIAN	Includes the Individual (Custodian) from whom the documents originated and all Individual(s) whose documents de-duplicated out (De-Duped Custodian)
DATE_CRTD	Date the document or attachment was created (format: MM/DD/YYYY)
DATE_MOD	Date the document or attachment was modified (format: MM/DD/YYYY)
DATE_RCVD	Date email was received (format: MM/DD/YYYY)
DATE_SENT	Date email was sent (format: MM/DD/YYYY)
EMAIL_SUBJECT	Subject line of email
ENDATTACH	Last production Bates number of the last document in a family

ENDBATES	Ending Bates number as stamped on the production image
FILENAME	File name of an electronic document or attachment
FILE_EXT	File extension of the native file
FILEPATH	File path of an electronic document or attachment
FILESIZE	Size of native file
FROM	The name and email address of the sender of the email
NATIVEFILE	Native File
PGCOUNT	Number of pages in a document or attachment
TIME_CRTD	Time the document was created (format: HH:MM:SS)
TIME_MOD	Time the document was modified (format: HH:MM:SS)
TIME_RCVD	Time email was received (format: HH:MM:SS)
TIME_SENT	Time email was sent (format: HH:MM:SS)
TO	All recipients that were included on the "To" line of the email
MD5HASH	Identifies the MD5 hash for the document

3. **TIFFs.** Documents that exist only in hard copy format shall be scanned and produced as TIFFs. Unless excepted below, documents that exist as ESI shall be converted and produced as TIFFs. Unless excepted below, single page Group IV TIFFs should be provided, at least 300 dots per inch (dpi) for all documents. Each TIFF image shall be named according to a unique corresponding Bates number associated with the document. Each image shall be branded according to the Bates number and the agreed upon confidentiality designation. Original document orientation should be maintained (i.e., portrait to portrait and landscape to landscape). TIFFs shall show all text and images that would be visible to a user of the hard copy documents.

4. **Text Files.** A single multi-page text file shall be provided for each document, and the filename should match its respective TIFF filename. A commercially acceptable technology for optical character recognition "OCR" shall be used for all scanned, hard copy documents. When possible, the text of native files should be extracted directly from the native file. Text files

will not contain the redacted portions of the documents and OCR text files will be substituted instead of extracted text files for redacted documents. All documents shall be produced with a link in the TextLink field.

5. **Image Load Files / Data Load Files.** Each TIFF in a production must be referenced in the corresponding image load file. The total number of documents referenced in a production's data load file should match the total number of designated document breaks in the Image Load file(s) in the production. The total number of pages referenced in a production's image load file should match the total number of TIFF files in the production. The total number of documents in a production should match the total number of records in the data load file.

6. **Bates Numbering.** All images must be assigned a unique Bates number that is sequential within a given document and across the production sets.

7. **Confidentiality Designation.** Responsive documents in TIFF format will be stamped with the appropriate confidentiality designations in accordance with the Protective Order in this matter. Each responsive document produced in native format will have its confidentiality designation identified in the slipsheet placeholder provided in TIFF format.

8. **Redaction Of Information.** If documents are produced containing redacted information, an electronic copy of the original, unredacted data shall be securely preserved in such a manner so as to preserve without modification, alteration or addition the content of such data including any metadata therein.

9. **Native Files.** Spreadsheets (e.g., MS Excel, Google Sheets), and delimited text files (e.g. comma-separated value (.csv) files and tab-separated value (.tsv) files) shall be produced in either their native format or MS Excel. TIFF images need not be produced unless the files have been redacted, in which instance such files shall be produced in TIFF with OCR Text Files. If good cause exists to request production of files, other than those specifically set forth above, in native format, the party may request such production and provide an explanation of the need for native file review, which request shall not unreasonably be denied. Any native files that are produced shall be produced with a link in the NativeLink field, along with extracted

text and applicable metadata fields set forth in Appendix 1. A TIFF placeholder indicating that the document was provided in native format and bearing the Bates production number should accompany the database record. If a file has been redacted, TIFF images and OCR text of the redacted document will suffice in lieu of a native file and extracted text.

10. **Proprietary Files.** To the extent a response to discovery requires production of ESI accessible only through proprietary software, the parties should continue to preserve each version of such information. The parties shall meet and confer to finalize the appropriate production format.

11. **Production Media.** Documents shall be encrypted and produced on external hard drives, readily accessible computer(s) or other electronic media, or via FTP or other equivalent ("Production Media"). Each piece of Production Media shall identify a production number corresponding to the production volume (e.g., "VOL001," "VOL002"), as well as the volume of the material in that production (e.g. "-001," "-002"). Each piece of Production Media shall be accompanied by an identification of: (1) the producing party's name; (2) the production date; and (3) the Bates Number range of the materials contained on the Production Media.

CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on July 11, 2023, I caused to be electronically filed a true and correct copy of Letter to the Honorable Sherry R. Fallon from Melanie K. Sharp Regarding Defendants' Letter (D.I. 236) with the Clerk of the Court using CM/ECF, which will send notification to the following counsel of record:

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I further certify that on July 11, 2023, I caused a copy of the foregoing document to be served on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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